Universitat de Girona
Facultat de Medicina

Trueta
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FINAL DEGREE PROJECT

Protocol for the implementation of intact cord management during neonatal resuscitation in the delivery room

A MULTICENTER RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Background: Intact cord management has proven benefits for heathy preterm and term newborns. An increased blood transfer reduces the incidence of neonatal complications and the need for transfusions or surfactant, but also increases the haematocrit, haemoglobin and iron stores at birth. Current guidelines only recommend this intervention during cardiopulmonary resuscitation when considered feasible during the "golden minute" assessment. The main objective of this clinical trial is to expand evidence on intact cord management during cardiopulmonary resuscitation, aiming to develop a standardised protocol for its implementation in the delivery room practice.

Design and participants: Multicentre, prospective, randomized, open-label, parallel-group clinical trial. Data managers and the statistician will be blinded to the group assignment and independent of the intervention.

All pregnant patients without any exclusion criteria admitted for labour to any of the hospitals included will be approached for consent. Before randomization, those newborns not requiring resuscitation will be excluded.

Setting: Seven hospitals from the "Servei Catalá de la Salut" will be involved in the study, which is expected to last five years, from sample recruitment to follow-up.

Intervention: 158 patients will be randomly assigned following a stratified randomization in a 1:1 ratio between intervention group (intact cord management) and control group (immediate cord clamping).

Outcome measures: The main outcome will be the Apgar score at 1, 5 and 10 minutes. Other shot-term outcomes include umbilical cord pH, blood pressure, septic and blood count parameters, complications and survival rates. For the long-term, neurodevelopmental outcomes will be evaluated using the Ages and Stages Questionnaires (3rd edition) during a period of 4 years.

Keywords: intact cord management, neonatal cardiopulmonary resuscitation, delivery room, Apgar score, umbilical cord pH, Ages and Stages Questionnaires.

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ABBREVIATIONS AND ACRONYMS

AAP	American Academy of Paediatrics
ACOG	American College of Obstetricians and Gynaecologists
AGA	Adequate for Gestational Age
AHA	American Heart Association
ASQ	Ages and Stages Questionnaire
BPM	Beats Per Minute
CEIC	Comité de Ética de Investigación Clínica
CPAP	Continuous Positive Airway Pressure
CPR	Cardiopulmonary Resuscitation
CRP	C-Reactive Protein
CSF	Cerebrospinal Fluid
DCC	Delayed Cord Clamping
DA	Ductus Arteriosus
DV	Ductus Venosus
ECC	Early Cord Clamping
ECG	Electrocardiogram
ELBW	Extremely Low Birth Weight
ERC	European Resuscitation Council
EU	European Union
FiO2	Fraction of Inspired Oxygen
GCP	Good Clinical Practice
Hb	Haemoglobin
Ht	Haematocrit
ICU	Intensive Care Unit

ILCOR	International Liaison Committee on Resuscitation
IPPV	Intermittent Positive Pressure Ventilation
IUGR	Intrauterine Growth Restriction
IVH	Intraventricular Haemorrhage
LGA	Large for Gestational Age
LOS	Late-onset Sepsis
MAP	Mean Arterial Pressure
MDV	Motor Development Vigour
mmHg	Millimetres of Mercury
NEC	Necrotizing Enterocolitis
NICU	Neonatal Intensive Care Unit
PBF	Pulmonary Blood Flow
PBCC	Physiological Based Cord Clamping
PCT	Procalcitonin
PEEP	Positive End-Expiratory Pressure
PIP	Peak Inspiratory Pressure
PVR	Pulmonary Vascular Resistance
REec	Registro Español de Estudios Clínicos
RDS	Respiratory Distress Syndrome
SENeo	Sociedad Española de Neonatología
SGA	Small for Gestational Age
SpO2	Saturation by Pulse Oximetry
UCC	Umbilical Cord Clamping
UCM	Umbilical Cord Milking
VLBW	Very Low Birth Weight

1. INTRODUCTION

1.1. Challenges of research in the delivery room

When conducting any kind of clinical trials there are always limitations, both ethical and methodological; but when these trials are developed inside of the delivery room when a mother gives birth, these issues are even bigger, which is what makes this investigation so challenging and limited. To begin with, research in the delivery room takes at least two patients, which are especially vulnerable, and the circumstances of both the delivery and support requirements for the mother and the newborn(s) cannot be predicted accurately before the time comes (1).

The first challenge that comes with this research is the informed consent, as approaching the mother during labour adds more stress to an already demanding time for them. In addition, the ethics of doing research in babies have been discussed as they are considered "vulnerable" populations, being excluded from several trials due to this, even more in terms of premature birth. As babies cannot consent themselves, they are dependent on their parents, who should have all the information of the study before deciding whether to take part in it. Providing sufficient information and having time to address any parental concerns is often not possible in delivery room studies, meaning parents need to rush in their decision of consent, which also limits the participation. This is the main reason why the standard approach is to obtain the consent during pregnancy (1,2).

Other issue enrolling research in the delivery room can be the difficulty of masking interventions for the purpose of the trial, being also challenging to identify the study outcome measures that are be sufficiently "short-term" to be influenced by the intervention, yet sufficient "long-term" to be considered clinically relevant. The struggle of masking the interventions is as well related with the amount of people in the delivery room, which tends to be crowded, making it practically impossible to mask most interventions and creating biases that can lead to a lower clinical significance of the study (2,3).

In addition, there is the matter regarding the timing of birth, which is also challenging, as many clinicians and other staff related to the study agree to participate within working hours, but most babies deliver “out of hours”, restricting enrolment to the study for office hours and having a lower recruitment and poor samples that are not representative of the real population, as the babies born “out of hours” are not included in the studies (2).

Clinical research has proved to be crucial to the evolution of medical care, and this includes investigation for newborns in the delivery room. Even though there are many barriers and challenges in researching with babies short after they are born, more research can lead to improvement in the delivery room clinical practice (2,3).

There is a need for studies across more fields of neonatal care, and this can only be done in the delivery room. We need to explore alternative consent approaches, such as deferred consent, improve masking methods, include more newborns to offset biases, and focus on collecting only the relevant outcomes, as the more information clinicians are asked to collect, the greater the risk of missing data or fabrication of it there is, leading to biassed results and lower significance (2).

1.2. Physiology of the newborn

It is important to understand the physiology of the newborn before and after umbilical cord clamping (UCC) to introduce the subject of this project. Cord clamping at birth is supposed to be the symbolical separation between the newborn and its mother. However, this process is way more complex than that, as it involves the moment where the newborn has to switch from the placental support to the lung aeration and redirect its blood flow into the different cavities of its heart (4).

To understand all this process, we should break it down step by step. To begin with, cardiovascular function before birth differs from the one after birth, as most of the right ventricular output bypasses the lungs, travelling from the main pulmonary artery into de descending aorta via the ductus arteriosus (DA), resulting in a low pulmonary blood flow (PBF). In consequence, the pulmonary venous return is also low and left ventricular preload primarily depends on the umbilical venous supply. The umbilical blood enters the ductus venosus or the liver, then returns to the heart via inferior vena cava, finally reaching the right atrium (4). Once in the heart, a significant portion of this oxygenated blood transfers to the left atrium via foramen ovale, serving a key preload source for the left ventricle, which then pumps blood to the systemic circulation. The left side of the heart ends up more oxygenated than the right side, whose deoxygenated blood proceeds from the upper fetal body via superior vena cava. Finally, low oxygenated blood is delivered to the placenta via he umbilical arteries to retrieve oxygen and nutrients, as the lungs do not perform their oxygenic exchange function in this stage (4,5). A diagram of this system's function is presented in Figure 1.

In terms of the respiratory function, during fetal life the airway and the lungs are full of liquid and, as a result, not aerated. The respiratory function during gestation is not developed, but the metabolism is indeed active, as this system is in constant movement to simulate the respiratory function, synthetises surfactant and secretes liquid into the potential aerated spaces (5).

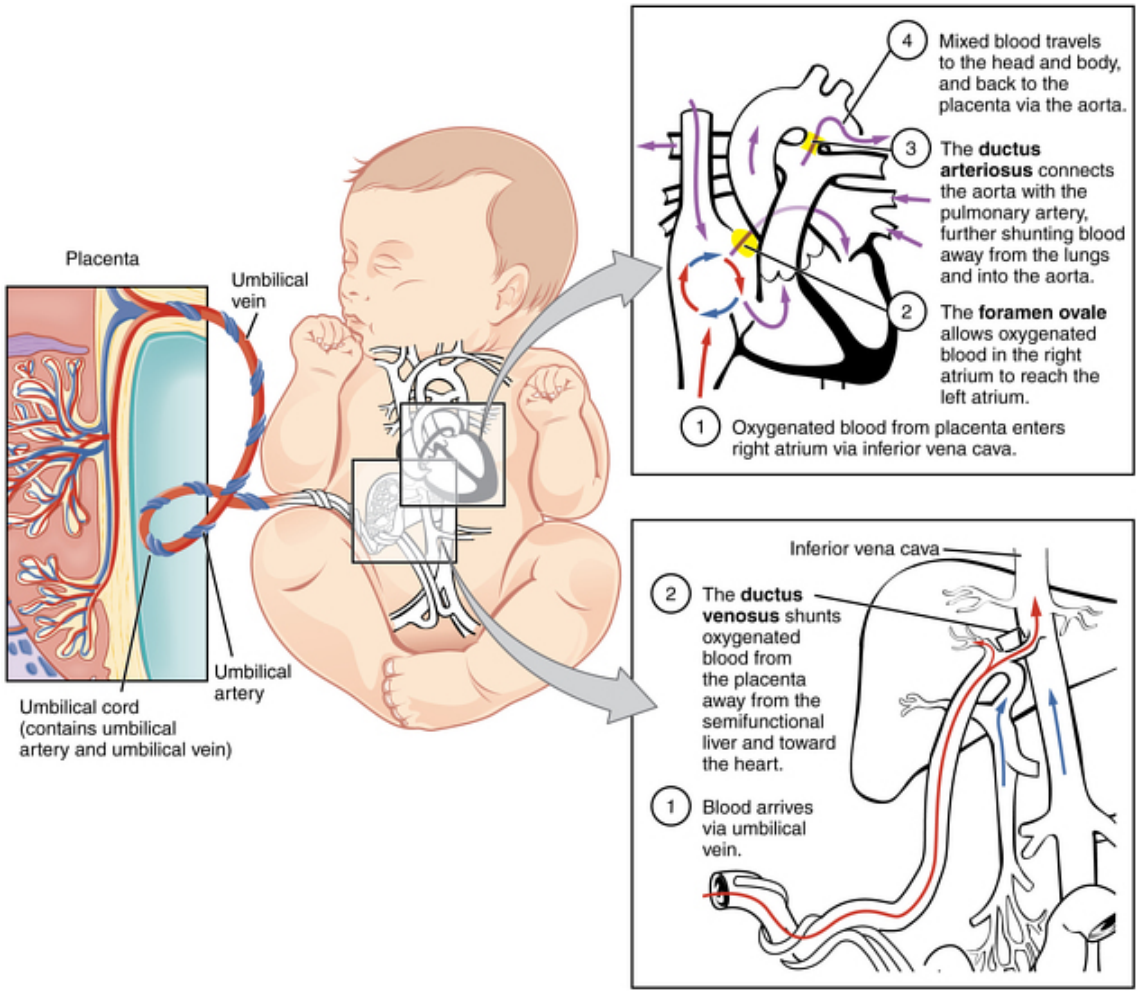

Figure 1. Fetal Circulation. *Oxygenated blood arrives via umbilical vein and enters the right atrium via inferior vena cava, afterwards it trespasses the foramen ovale into the left atrium and connects to the aorta by the DA to travel the body and back to the placenta to retrieve oxygen and nutrients (3).*

After birth, the newborn's physiology changes significantly to cope with the new environment he/she is now in. This transition begins with lung aeration. The newborn must clear its airways of liquid and initiate pulmonary gas exchange, a crucial step for adapting to life outside of the womb. This gas exchange triggers a huge decrease in the pulmonary vascular resistance (PVR) and increase in pulmonary blood flow (PBF), just the opposite of what occurred during fetal state, resulting in the initial transition to the adult circulatory system (4,6).

Once pulmonary exchange begins, the reduction in pulmonary vascular resistance (PVR) increases venous return from the lungs into the left atrium, compensating for the reduction of blood flow coming from the placenta and a decreased volume entering the left atrium due to a diminished flow through ductus venosus (DV) (4). Both these factors lead to an equalization of the atrial pressures, facilitating the functional closure of the foramen ovale within the first 48 hours. Simultaneously, the flow through the ductus arteriosus (DA) reverses, making the left ventricular output become a major contributor of the pulmonary blood flow. These neonatal changes are illustrated in Figure 2 (4,7).

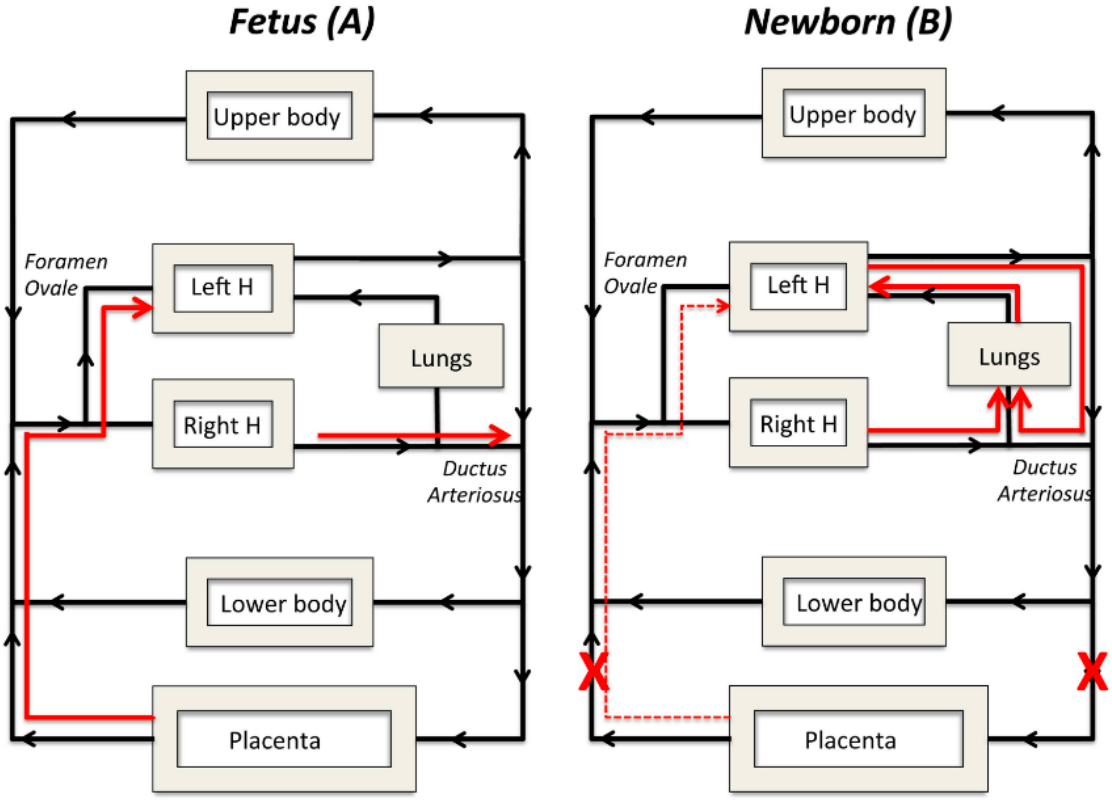

Figure 2. A schematic of the fetal circulation before birth and the changes in flow that occur after birth. *Before birth the major supply of preload for the left ventricle is derived from the placental circulation, which enters the left side of the heart; thereby bypassing the right side of the heart and the lungs via DA (A; pathway shown by red arrow). After birth, the supply of blood for the left ventricle derived from the placental circulation is lost (B; broken red arrow) and so preload for the left ventricle becomes dependent on pulmonary venous return (B; red arrow). For this to occur, the lung must first aerate, which decreases the PVR, allowing all the right ventricular output to pass through the lungs (B; red arrow). In addition, flow through the DA reverses so that left ventricular output becomes a major contributor to pulmonary blood flow and, therefore to pulmonary venous return as well (4).*

One aspect that might require further explanation is the increase of pulmonary blood flow (PBF) after birth. Traditionally, this has been associated with changes in the blood oxygenation related to the initiation of pulmonary gas exchange. However, recent studies have questioned this assumption, demonstrating that in some animal models PBF increases independent of changes in oxygen levels, using for example partial lung aeration with nitrogen, among others (6,8).

To fully understand these changes in the physiology of the newborn, we should take one step further into the physiology of the umbilical cord, which is considered both the physical and emotional connection between the mother and the fetus. The umbilical cord enables the transfer of oxygen and nutrients from the maternal circulation via the umbilical vein, while removing waste products from the fetal circulation via the two umbilical arteries. These arteries converge near the insertion of the cord forming Hyrtl's anastomosis, which helps equalize the pressures as blood enters the placenta forming the chorionic vessels. After birth, these vessels reduce their blood flow, and the cord stops pulsating, changing the physiology of the newborn entirely, as discussed previously (9).

1.3. Umbilical cord management

The umbilical cord clamping (UCC) is a crucial step during the third stage of labour, and it separates the newborn from the placenta. There is considerable controversy regarding the optimal timing for UCC once the baby has been delivered. We need to differentiate early cord clamping from delayed cord clamping and their multiple variations and techniques (10).

Early cord clamping (ECC) is defined as clamping the umbilical cord within the first 30 seconds of birth, and it is usually performed in the first 10-15 seconds. This strategy reduces the amount of blood transfused from the placenta to the newborn and has been associated with negative neonatal outcomes such as hypoxia, infections, anaemia and delayed psychomotor development (10–12).

Delayed cord clamping (DCC), on the other hand, refers to the practice of clamping the umbilical cord at least 30 seconds after birth, or when the blood pulsations have stopped, and the ventilation has been stablished. These cardiorespiratory markers are also applied to the term of physiological based cord clamping (PBCC). Frequently DCC/PBCC occurs 1-3 minutes after birth, because it is at 3 minutes approximately when placental transfusion ends. The aim of PBCC is to ensure aeration of the lungs, adequate blood flow and gas exchange before retrieving the newborn's access to maternal blood flow from the placenta through the umbilical cord. DCC has reported having better neonatal outcomes and benefits which are explained in further detail in the next section of this introduction (10,13).

Finally, another cord management strategy is the umbilical cord milking (UCM), which consists in the propulsion of blood through the umbilical cord clamped or unclamped 3-4 times in direction of the newborn in approximately 20 seconds (14). This strategy has been recommended in specific situations by international associations; however, as it is not endorsed by the "Sociedad Española de Neonatología" (SENeo), it will not be discussed further in this project (15).

1.4. Benefits of delayed cord clamping

Until recently, the benefits and risks associated with delayed cord clamping (DCC) were primarily attributed to placental blood transfusion towards the baby. This transfusion increases the blood flow to the baby, potentially decreasing the risk of blood transfusions. However, there is no evidence supporting that this transfusion occurs inversely resulting in anaemia in the neonate, so this is not considered a risk of DCC. Evidence shows that placental blood continues to flow in direction to the baby after birth. Nonetheless, several other factors contribute to the increase of the infant's blood flow, such as the lung aeration, which has been proven to be a key aspect in enhancing the pulmonary blood flow (PBF) (4,10).

The transition into neonatal circulation during birth is governed by both these processes: the start of breathing and the shift away from umbilical cord blood flow. Therefore, understanding the possible positive effects of DCC requires studying it alongside the onset of breathing (16).

Once aeration begins, the cardiac output rises along with the PBF, and this also increases the venous return and ventricular preload. The main advantage of delaying cord clamping is that it allows more time to pass an extra 40% blood volume from the placenta to the newborn (16). This increase improves the haematological status of full-term babies, raising haemoglobin (Hb) concentrations, haematocrit (Ht) levels, and iron stores up to 6 months after birth. This prevents the development of iron deficiency or anaemia, especially in infants living in low-resource settings with less access to iron-rich foods (10,16,17). Furthermore, iron plays an important role in neurodevelopment of the newborn, in particular, iron deficiency makes it more likely to develop delayed psychomotor development and up to 10-point deficits in intelligence quotients. There is evidence that these impairments may be irreversible even after iron repletion. Some studies have shown that a delay of 30-60 seconds in cord clamping improves short-term neurobehavioral outcomes in late preterm infants (34-36 weeks), having higher scores in both motor development vigour (MDV) and alertness orientation (11).

The Ages and Stages Questionnaire (ASQ) allows the assessment of infant development by parent-reported information (18). It has proven to be reliable and have adequate correlation and ability to predict difficulties in neurodevelopment up to 4 years of age (19). Furthermore, the ASQ has been already used to evaluate neurodevelopment in relation with delayed cord clamping by Andersson et al. (20).

Another significant haematological outcome from DCC is the increase of blood pressure, in both term and preterm infants, contributing to improve the haemodynamic features and organ perfusion (11).

Regarding respiratory function, DCC has been associated with increased pulmonary circulation and cardiac output, facilitating greater oxygen delivery to the tissues and supporting the onset of spontaneous breathing. Furthermore, this practice has been linked to a reduced risk of respiratory distress syndrome (RDS) in premature populations and a decreased need of respiratory support (11).

The Apgar score is the standardized method for assessing the adaption and vitality of the newborn, carried out the first minutes after birth (21). There has been some controversy in different clinical studies regarding the relation of DCC and Apgar score. Nevertheless, most research has found no significant difference in both 1-minute and 5-minute Apgar scores in newborns, suggesting that DCC does not have a notable impact in these measures (11).

Another feature related to Apgar score is the acid-basic status in umbilical cord blood, which reflects the newborn's intrauterine metabolism and is an objective measure of fetal exposure to hypoxia. Arterial umbilical cord blood gas analysis (BGA), including umbilical cord pH, is essential to define neurologic complications associated with intrapartum situations like hypoxia. Results from several clinical studies that evaluated umbilical cord BGA related to DCC are inconsistent and delivered no clear conclusions. According to Qian et al. further studies are needed to explore the effect of DCC on BGA in high-risk newborns (11).

Regarding the immune system, extended placental transfusion after birth promotes the transfer of immunoglobulins and stem cells, both essential for organ and tissue

repair. These elements are particularly beneficial for preterm babies as they develop higher rates of cellular injury, inflammation and organ dysfunction. Additionally, they contribute to immunocompetence, reducing the vulnerability to inflammatory processes, and resulting in a lower risk of late-onset sepsis (LOS), defined as the development of an infection involving the bloodstream in newborns occurring after 72 hours of life (11,22,23).

In terms of the endocrine system, delayed cord clamping enables the passage of hormones such as beta-endorphin or prolactin, resulting in higher levels in the newborn and enabling a faster mother-infant attachment and breastfeeding success. Exposure to beta-endorphins also motivates both the mother and the baby to extend breastfeeding while strengthening their postnatal interaction. This also promotes prolactin secretion, a critical factor for breastfeeding success and maternal-newborn bonding (24).

Moreover, growing evidence suggests that delayed cord clamping (DCC) at least 30-60 seconds, promoting placentofetal transfusion, offers immediate benefits. These include a reduction in the risk of intraventricular haemorrhage (IVH), necrotizing enterocolitis (NEC) and late-onset sepsis (LOS), as well as an increase of blood pressure at 1 and 4 hours after birth. Additionally, it decreases the need for interventions such as blood transfusions, surfactant and mechanical ventilation in preterm (< 32 weeks) or low-birth-weight infants (17,25).

There have been concerns regarding the risks of DCC for mothers, particularly in postpartum haemorrhage, which affects approximately 2% of them and contributes to maternal mortality and morbidity in most low-income countries. Initially, early cord clamping (ECC) was believed to be essential in the management of the third stage of labour to prevent postpartum haemorrhage. However, revisions of those protocols recommend otherwise, as current evidence shows that performing DCC does not affect maternal bleeding or the duration of the third stage of labour. Another significant outcome for the mothers is the reduced risk of placental retention associated with DCC (17).

All these benefits for infants and mothers, based on the results of different types of studies, are summarized in Table 1. The image presented in Figure 3 is a graphic representation of the different systems where DCC has an effect.

Immediate benefits			Long-term benefits	
Preterm/low-birth-weight infants	**Full-term infants**	**Mothers**	**Preterm/low-birth-weight infants**	**Full-term infants**
Decreases risk of: • intraventricular haemorrhage • necrotizing enterocolitis • late-onset sepsis	Provides adequate blood volume and birth iron stores	No effect on maternal bleeding or length of the third stage of labour	Increases haemoglobin at 10 weeks of age	Improves haematological status (haemoglobin and haematocrit) at 2–4 months of age
Decreases need for: • blood transfusions for anaemia or low blood pressure • surfactant • mechanical ventilation Increases: • haematocrit • haemoglobin • blood pressure • cerebral oxygenation • red blood cell flow	Increases: • haematocrit • haemoglobin	Indication from "cord drainage" trials that less blood-filled placenta shortens the third stage of labour and decreases the incidence of retained placenta	May be a benefit to neurodevelopmental outcomes in male infants	Improves iron status up to 6 months of age

Table 1. Summary of immediate and long-term benefits of delayed umbilical cord clamping for infants (term, preterm/low birth weight) and mothers (17).

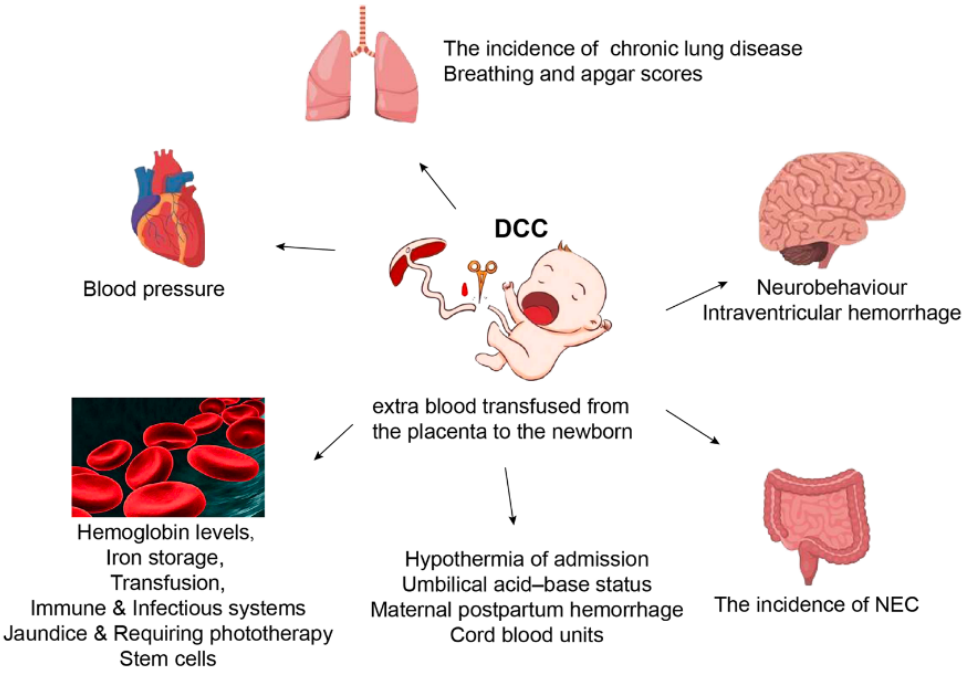

Figure 3. Systems affected by delayed cord clamping in the newborn (11).

1.5. Neonatal cardiopulmonary resuscitation

Most newborns adapt well to extrauterine life and do not require resuscitation or stabilization. Approximately 85% breathe spontaneously without intervention, another 10% respond to stimulation manoeuvres, and only about 5% require further assistance. Risk factors contributing to the need for resuscitation include antenatal situations such as delayed intrauterine growing, preterm birth (less than 37 weeks of gestation), oligo/polyhydramnios, maternal infections, preeclampsia, and labour complications like meconium-stained amniotic fluid, breech presentations, significant bleeding and caesarean section before 39 weeks (26).

When resuscitation is needed, it involves different phases. First of all, it is very important to have trained personnel who can implement effective team behaviours such as communication, briefing or role assignment, among others (27).

The initial assessment of the newborn should answer 3 questions (15):

- Is the gestation in term?
- Is the baby breathing or crying?
- Does he/she have a good muscular tone?

If the answer to any of these questions is negative, immediate action should be taken to stabilize the newborn during the "golden minute", which includes the initial ventilation manoeuvres. Special attention should be given to the first question, as late preterm newborns that demonstrate a satisfactory response to the other two questions could be treated like term newborns. The first five steps of neonatal resuscitation are as follows (15):

1. Consider the delayed cord clamping (DCC) if this is feasible during the initial steps of cardiopulmonary resuscitation (CPR) (15).
2. Stabilize heat loss placing the newborn under a heat font, using warm towels and avoiding currents in the delivery room to maintain the newborn's temperature between 36,5 and 37,5ºC (15,26).

3. Optimize the airway by placing the newborn in a correct position (supine position with light extension of the neck or neutral position of the head), and aspiring secretions if there is an obstructed airway (15).
4. Dry the body and provide tactic stimulation by rubbing the foot or the back of the newborn (15,26).
5. Position the head to align the airway with a neutral position (it is also possible to pull the mandible forward to open the airway) (15,26).

If the newborn fails to establish an adequate and regular breathing or the heartrate is below 100 bpm, cardiopulmonary resuscitation (CPR) manoeuvres need to be started (26). As it has already been stated before, the first thing any newborn needs in order to have an adequate transition to extrauterine life is a correct breathing so, the primary objective neonatal CPR is to establish effective ventilation (28).

Once the airway is clear, the first measure is to start intermittent positive pressure ventilation (IPPV) at a 21% fraction of inspired oxygen (FiO2) during 30 seconds with a ventilator and humidified heated gasses ideally in a frequence of 40-60 breaths per minute, positive end-expiratory pressure (PEEP) 5-7 cmH_2O and peak inspiratory pressure (PIP) 25-30 cmH_2O (20-25 cmH_2O in preterm infants). If ventilation is ineffective, suctioning of secretions under direct vision of the respiratory field may be necessary (29,30).

Monitoring of the vital signs is crucial, using an electrocardiogram (ECG) to track a reliable heart rate (HR), a pulse oximeter to measure the oxygen saturation (SpO2), and monitoring the respiratory function, including ventilatory volumes (15).

Regarding oxygen therapy, we should differentiate two groups: term or late preterm newborns (> 35 weeks), to whom the Liaison Committee on Resuscitation (ILCOR) recommends a FiO2 21% for the initial steps of resuscitation; and very preterm infants (< 35 weeks), to whom the ILCOR recommends FiO2 21% in 30-35 weeks, FiO2 30% in < 30 weeks and FiO2 40% in < 28 weeks (15).

Most non-vigorous newborns, defining non-vigorous as poor tone, pale colour or lack of breathing in the first 15 seconds after birth, respond well to these initial steps

of CPR including an effective IPPV with a rise in heart rate and improved breathing, but there are some who might remain irresponsive despite these interventions (27,31). If a newborn remains under 60 bpm, chest compressions might be effective to supply their brain with oxygenated blood (27). The FiO2 must be increased to 100% and ventilation must be optimized, even by placing an endotracheal intubation (26,27). Once the chest compressions have started, there needs to be a synchronized technique, with a rhythm of 3:1 ratio (making three compressions for every ventilation) in approximately 15 cycles every 30 seconds, reassessing the newborn status every 30 seconds (26).

If the chest compressions or the IVPP prove ineffective or prolonged in time, orotracheal intubation using an endotracheal tube and a laryngoscope should be attempted. Intubation should not last more than 30 seconds, and the heartrate must remain above 100 bpm. If the intubation is unsuccessful, the use of a laryngeal mask should be considered in newborns over 34 weeks or over 1500-2000g (15).

When performing advanced cardiopulmonary resuscitation (ACPR), it may be reasonable to seek for intravascular access to infuse drugs and/or volume expanders. The main venous access should be the umbilical vein in the delivery room, reassuring a locked system to avoid gaseous embolism. In case this approach is not available, the intraosseous route can be a good alternative (26,27).

During active resuscitation, the main medications include epinephrine to boost heart rate, glucose to prevent hypoglycaemia, and volume expanders such as saline solutions, Ringer lactate or blood 0 Rh negative if there is hypovolemia. There are some medications only used in specific situations: sodium bicarbonate, for example, is not recommended during resuscitation manoeuvres unless they last longer than 10-15 minutes and there is severe metabolic acidosis demonstrated with a blood sample; or intramuscular naloxone, recommended only in persistent apnoea in situations where the mother might have taken opioids (26,32).

There is a special group regarding resuscitation which is the one including very preterm newborns (28-32 weeks) and extreme preterm newborns (< 28 weeks) in which the necessary therapeutic procedures include precise temperature control,

adequate humidification, minimal manipulation procedures and different targets in ventilatory support dure to their fragility and immaturity. And it is because of their increased vulnerability that both these groups develop a higher risk of hypothermia, respiratory depression, hemodynamical instability and intraventricular haemorrhage, among others (15).

For extreme preterm newborns (< 28 weeks), initial management should focus on three key aspects: hypothermia prevention, breathing management and surfactant administration. These following main points must be considered (15):

- Preventing hypothermia by maintaining the room temperature around 26ºC, heating the thermal crib at 38ºC before labour, drying the newborn, using an occlusive wrap or a polyethylene bag to avoid heat loss and maintain humidity, and using humidified hot gasses in resuscitation (15).
- Using continuous positive airway pressure ventilation (CPAP) for breathing management, as it avoids barotrauma or overdistension injury, and atelectotrauma (alveolar collapse) (15).
- Administration of surfactant within 2 hours of life in infants with respiratory distress syndrome (RDS) to reduce mortality and other complications (bronchopulmonary dysplasia and air leaks) (15).

The current neonatal life support algorithms for both preterm (<32 weeks) and term infants developed by the “Sociedad Española de Neonatología” (SENeo) and available in their 2021 Guidelines for Stabilization and Resuscitation are presented in Figures 4 and 5.

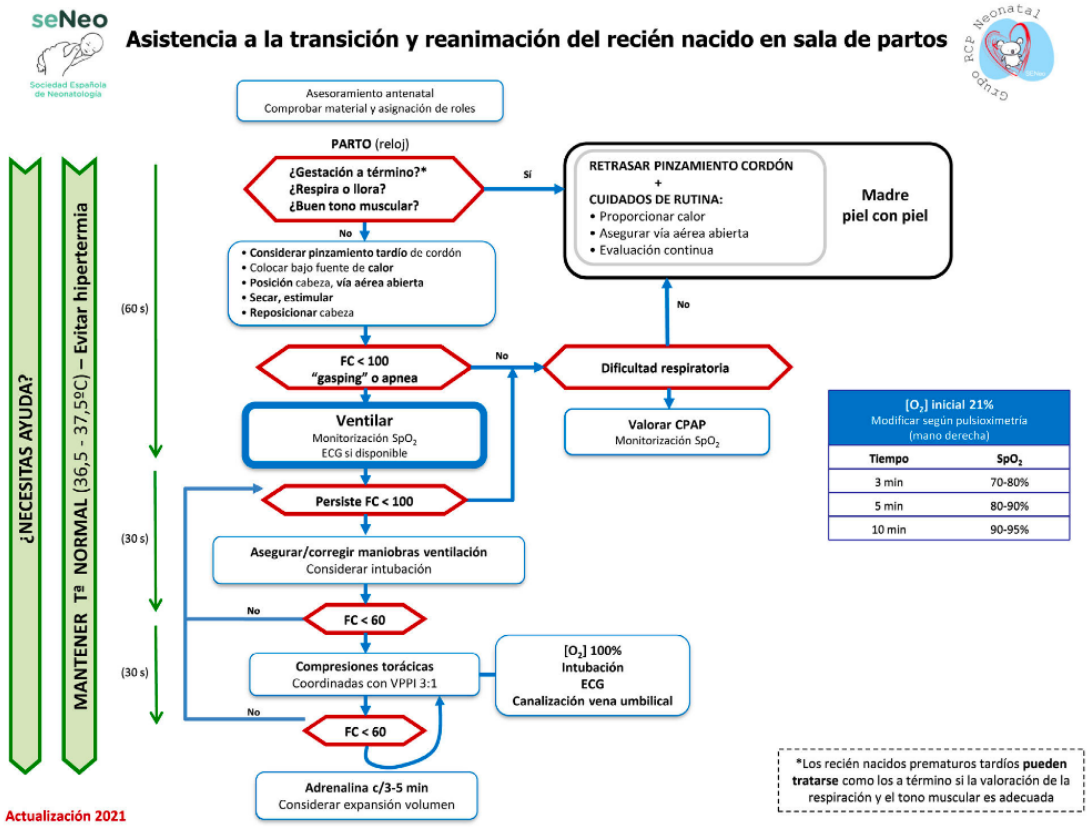

Figure 4. Neonatal generical life support algorithm (30).

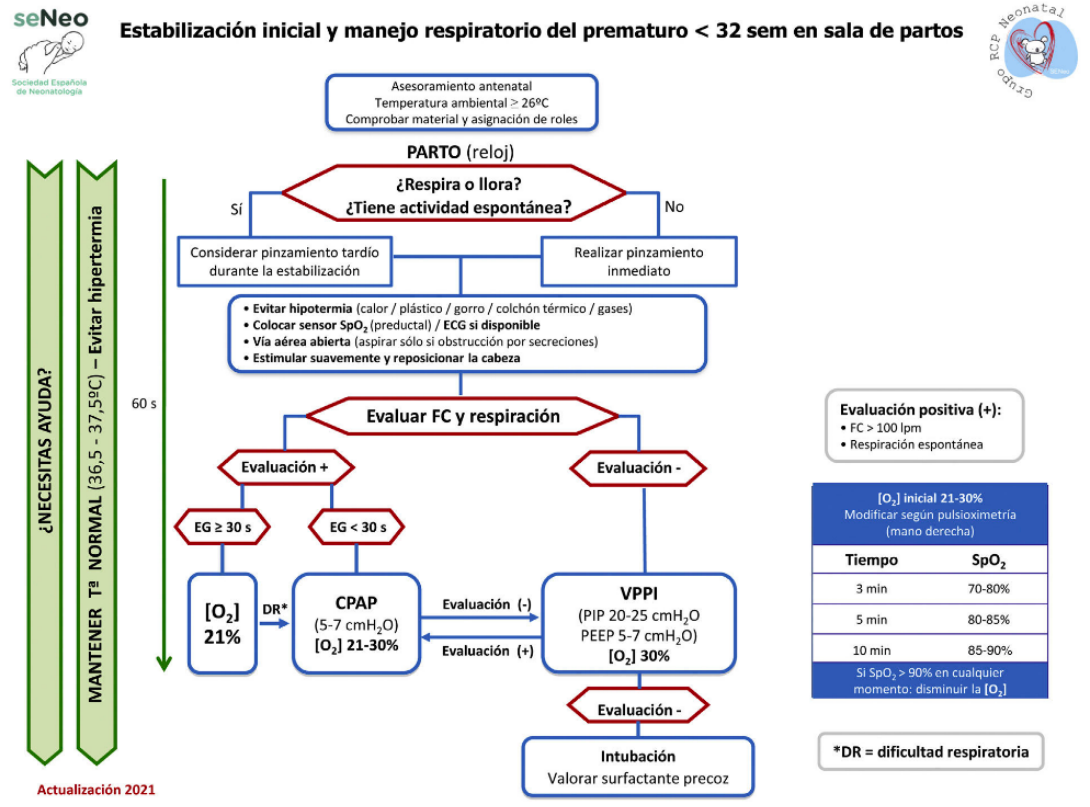

Figure 5. Stabilization and breathing management in preterm infants < 32 postmenstrual weeks (30).

1.6. Integrating neonatal resuscitation with cord management

Once we understand the standard practices for neonatal resuscitation, it is necessary to integrate these with the management of the umbilical cord, aligning with the current recommendations.

Before delving into the comprehension of cord management during resuscitation manoeuvres, it is important to recognize that this is an area requiring further robust investigation. Developing new guidelines is fundamental to provide clear and strong recommendations regarding cord clamping (28).

The 2023 American Heart Association (AHA) and American Academy of Paediatrics (AAP) guidelines support the possibility of delayed cord clamping (DCC) during the first steps of the neonatal resuscitation, such as drying and evaluation of the newborn (30). In terms of vigorous newborns, they divide them into two groups: the first one includes term and late pre-term newborns (34-42 weeks), and the second one includes very preterm and extreme preterm newborns (< 34 weeks). Regarding both groups, they state that "delaying cord clamping can be beneficial when compared to early cord clamping (< 30 seconds)". Recommendations in non-vigorous infants are still too weak and require further investigation (28).

The International Liaison Committee on Resuscitation (ILCOR) also suggests that DCC could be associated with benefits in infants before 34 weeks. Whereas the European Resuscitation Council (ERC) recommends delayed cord clamping at least 60 seconds in all newborns not requiring resuscitation, considering physiologically based cord clamping if feasible and safe (30).

The "Sociedad Española de Neonatología" (SENeo) recommends initiating stimulation or initial ventilation maneuvers while keeping the umbilical cord intact, provided it is feasible and safe, and within a locally agreed-upon protocol (15,30).

Despite this information, all these national and international societies acknowledge that the current evidence available in this subject is limited and there is a need to elaborate agreed-upon protocols. They only consider the performance DCC if

feasible (for example, using CPR trolleys positioned close to the mother) and safe for the onset of ventilation manoeuvres. Any other resuscitation scenarios are generally excluded from DCC recommendations, considering it only within the framework of the “golden minute” assessment (15,28,30).

For persistent cord integrity during CPR to be feasible, trained personnel and appropriate materials are essential in the delivery room. To perform an adequate resuscitation while leaving the cord unclamped there is different resuscitation equipment available nowadays, Among the different options, the discussion will focus on two devices: LifeStart™ Bed and Concord Birth Trolley (33).

The LifeStart™ Bed (Figures 6 and 7), developed by the Inspiration HealthCare group in the United Kingdom, consists in a small, mobile, and adjustable trolley equipped with a warming mattress. The mattress uses Inditherm proprietary carbon polymer technology that allows temperature adjustments between 35ºC and 40ºC. The latest version of the trolley also allows an increase range of vertical movement to adjust to the both the mother and the midwife/gynaecologist (33,34).

Sterile drapes are available for use in the delivery room to preserve the sterile field. Additionally, medirails are fitted to carry medical equipment such as gas cylinders, neonatal warming system, suction system, air/oxygen blender, flowmeter and a Neopuff resuscitator with end-tidal CO2 detector (33,35).

Regarding the pros and cons of the LifeStart™ Bed: the most significant advantages include portability, size and inclusion of essential equipment. Moreover, it has been validated in multiple studies as it was the first ever available trolley specifically designed for this purpose. However, the primarily limitations are its inability to transmit sufficient heat with the bed (40ºC maximum) and the lack of integrated accessory resuscitation material (33).

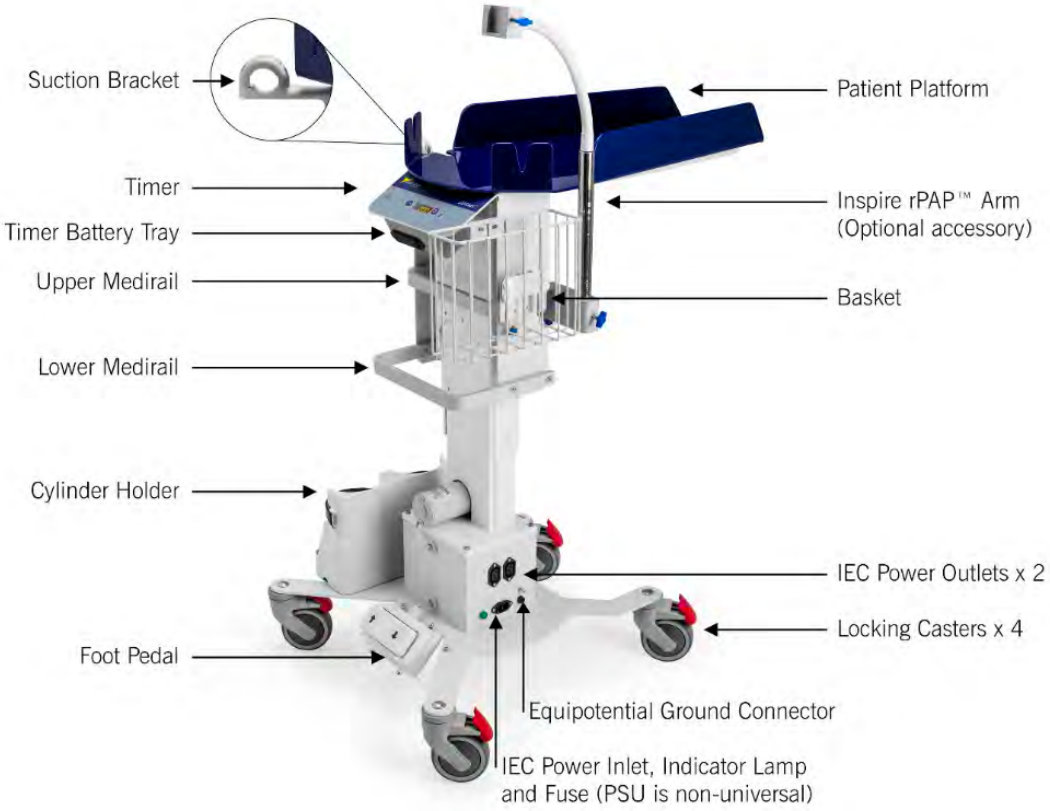

Figure 6. LifeStart™ Base Unit (35).

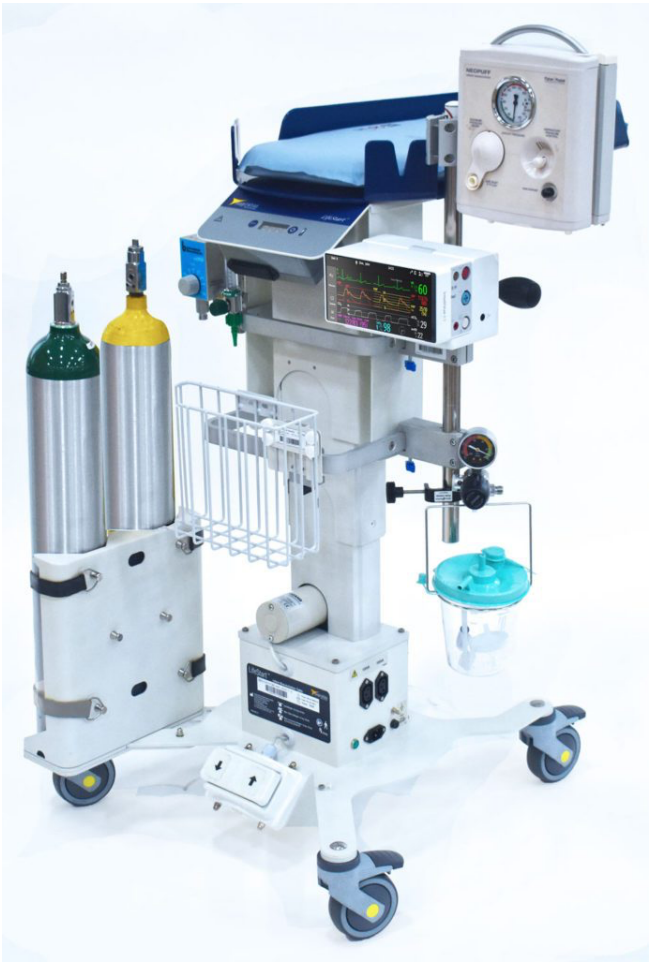

Figure 7. LifeStart™ Delayed Cord Clamping System (36).

The Concord Birth Trolley (Figure 8), developed by the Leiden University Medical Centre, consists in a height-adjustable platform with a slit for the umbilical cord. This design allows the platform to be positioned above the mother's pelvis, minimizing cord tension during resuscitation. This trolley can be equipped to support neonatal resuscitation with features such as a radiant heater, humidifier, heated resuscitation circuit T-piece ventilator, pulse oximeter, oxygen blender and suctioning equipment (33,37). Besides, additional instruments like a respiratory monitor, a cerebral oximeter, or up to two gas tanks can be integrated. During caesarean deliveries, the Concord can also be easily draped sterile (33,37).

Regarding the pros and cons of using this kind of trolley: the Concord allows optimal placement due to the height-adjustable rotating platform, not interfering with the obstetrical workspace. It also accommodates additional advanced resuscitation equipment. However, with all this equipment, the trolley becomes heavy and robust, making the manoeuvres challenging in small delivery rooms. Furthermore, it does not allow neonatal transportation to the intensive care unit (ICU) (33).

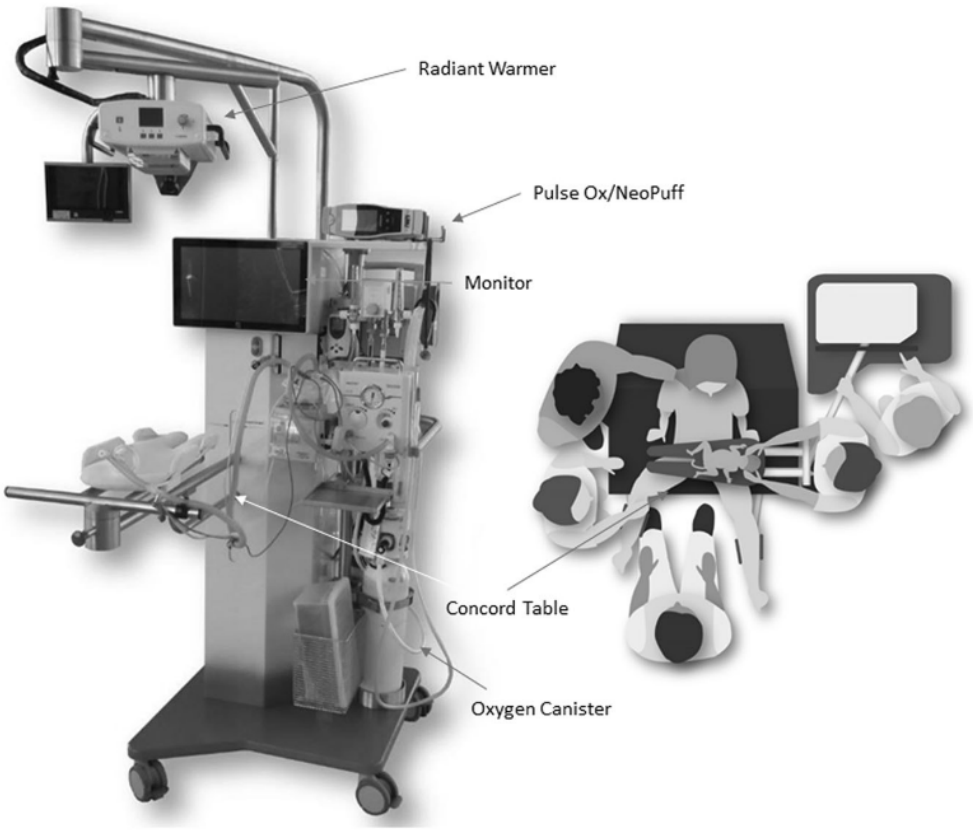

Figure 8. Concord Birth Trolley. *Labelled prototype (left panel). Sketch of trolley during delivery (right panel) (33).*

Table 2 presents a comparison between the LifeStart and Concord trolleys, allowing us to discern the key differences between them.

	Radiant heat	**Height-adjustable**	**Swivel function**	**Ability to mount additional equipment**	**Independent gas supply**	**Independent electric supply**
LifeStart™	No, chemical mattress	Yes	No	Yes	Can mount underside tanks	No
Concord	Yes, radiant heater	Yes	Yes	Yes	Yes	No

Table 2. Summary of differences between different trolleys adapted from Katheria et al. (33).

Finally, to perform resuscitation manoeuvres with an intact cord, the presence of a multidisciplinary team is essential. At minimum, this includes a gynaecological team to manage the delivery and a neonatology team to assist the newborn. The resuscitation team primarily consists of neonatologists and NICU nurses, both trained in neonatal life support and especially skilled in operating the selected resuscitation trolley and its associated equipment. For any labour, at least one professional trained in neonatal resuscitation needs to be present. However, for high-risk deliveries, a professional trained in advanced CPR should be present, and if advanced resuscitation becomes necessary, two trained professionals will be required to perform such techniques. Additionally, other assistant nurses may be required and should be available to support the team as needed (15,34,38).

2. JUSTIFICATION

Most newborns transition effectively to extrauterine life without the need for stabilization. Approximately 85% breathe spontaneously within the first 30 seconds after birth without intervention; another 10% respond to drying and tactile stimulation, while about 5% require further assistance (26,39). Moreover, in preterm newborns < 32 weeks, as well as in very low birth weight (VLBW, <1500 g) and extremely low birth weight newborns (ELBW, <1000 g), these percentages increase significantly (26,39,40).

The ideal scenario would involve identifying newborns requiring resuscitation before birth and ensuring trained neonatal resuscitation teams available and ready to perform these manoeuvres at the delivery room. Unfortunately, no current strategies allow medical teams to foresee the need for resuscitation, making it necessary for resuscitation teams to be available in all births (39).

When delivering resuscitation, as it has already been explained, current guidelines acknowledge that the evidence available in delayed cord clamping (DCC) during CPR is limited and there is a need to elaborate agreed-upon protocols. The national and international societies only consider the performance DCC if feasible and safe for the onset of ventilation manoeuvres. Any additional resuscitation scenarios are generally excluded from their recommendations, considering its performance only within the framework of the “golden minute” assessment (15,28,30).

Regarding the current evidence available on this subject, few studies among the many available on DCC have included non-vigorous infants, as it is often a exclusion criterion (12,16). However, recent research has begun to address this gap.

Nepcord III, a randomized clinical trial which compared intact cord resuscitation with early cord clamping before resuscitation in newborns 34-41 weeks, demonstrates the benefits from DCC during resuscitation manoeuvres such as an increased oxygen saturation, decreased heart rate and higher Apgar scores, all

these significant findings. Furthermore, the absent of negative consequences encourages further studies with longer follow-up according to Andersson et al. (41).

Another randomized trial of cord clamping and initial stabilization at very preterm birth, before 32 weeks, regardless of the mode of birth or fetal presentations found significant reduction in death and intraventricular haemorrhage (IVH) rates. According to the authors, the improvement outcome needs to be addressed in a larger trial. This study already demonstrates that such trial is feasible (42).

Finally, a meta-analysis on umbilical cord management in newborn resuscitation that included six studies concluded that "intact cord management during resuscitation appears to be a safe intervention". They also imply that it is necessary to develop further high-quality randomized clinical trials with larger number of patients urgently (43).

The foundation of our study is the need of larger groups to investigate the benefits of intact cord management in newborns of any gestational age during all resuscitation manoeuvres, as most of these studies only included initial ventilation among their interventions (43). Furthermore, Spanish population is not represented in these international studies so, to develop agreed-upon protocols, local clinical trials must be developed, being this the main aim of our study.

Finally, as we already know, receiving an adequate blood volume from placental transfusion at birth is protective for neonates, and studies suggest that those requiring resuscitation need their placental transfusion extended even more, as it plays a major role in preventing hypovolemia and providing better organ perfusion (44). Maintaining the cord intact provides this extended blood flow along with many other benefits already mentioned in this protocol, which justifies this study further.

Expanding knowledge about intact cord management during cardiopulmonary resuscitation in the delivery room is crucial. By identifying its benefits, we can develop evidence-based protocols for this practice. Although this has been excluded from many studies, it is the primary focus of our own.

3. HYPOTHESIS

3.1. Main Hypothesis

Maintaining the cord intact during neonatal resuscitation in the delivery room has a positive impact on short-term clinical outcomes such as Apgar scores and umbilical cord pH in non-vigorous newborns.

3.2. Secondary Hypothesis

- Intact cord management during neonatal resuscitation enhances haemodynamic stability, improves septic parameters, and optimizes haematological status in non-vigorous newborns.
- Intact cord management during neonatal resuscitation reduces the neonatal complications of non-vigorous newborns.
- Intact cord management during neonatal resuscitation improves the survival rates of non-vigorous newborns.
- Intact cord management during neonatal resuscitation improves long-term neurodevelopmental outcomes in non-vigorous newborns.

4. OBJECTIVES

4.1. Main Objective

To evaluate the impact of intact cord management during neonatal resuscitation in the delivery room on immediate clinical outcomes of non-vigorous newborns, as measured by Apgar scores at 1, 5 and 10 minutes and umbilical cord pH at 5 and 20 minutes, with the aim to elaborate a standardized protocol for the implementation of this practice.

4.2. Secondary Objectives

- To explore the benefits of a prolonged placental transfusion by assessing blood pressure, septic parameters (procalcitonin (PCT) and C-reactive protein (CRP) and blood count parameters (haemoglobin and haematocrit) within the first 7 days of life.
- To evaluate the rate of neonatal complications such as respiratory distress syndrome (RDS), intraventricular haemorrhage (IVH), necrotizing enterocolitis (NEC) or late-onset sepsis (LOS) in newborns with an intact cord during resuscitation at hospital discharge.
- To assess survival rates 12-36 hours after birth of newborns requiring resuscitation with an intact cord.
- To measure the neurodevelopmental outcomes of newborns who underwent resuscitation with an intact cord at 6, 12, 24 and 42 months of corrected age using the Ages and Stages Questionnaires (3rd edition).

5. METHODOLOGY

5.1. Study design

To elaborate a standardized protocol for the implementation of intact cord management during neonatal resuscitation, the accomplishment of the objectives of this study is necessary. We propose the performance of a multicentre, prospective, randomized, open-label, parallel-group clinical trial.

This study will include newborns of any gestational age above the limit of viability (23 weeks) who meet the resuscitation criteria and do not meet any of the exclusion criteria, and whose parents sign the informed consent (Annex 2). All patients included will be randomly assigned into the following two groups in a 1:1 ratio:

- **Intervention group:** non-vigorous newborns where intact cord management is performed during neonatal resuscitation.
- **Control group:** non-vigorous newborns where immediate cord clamping is performed during neonatal resuscitation.

This clinical trial aims to evaluate the feasibility of intact cord management implementation and to compare clinical outcomes between the intervention and control groups. The principal outcome to assess will be Apgar score at 1 minute, 5 minutes and 10 minutes of life.

Ethical approval will be solicited for the implementation of intact cord management and the prospective data collection for both intervention and control groups.

It is crucial to note that in case new evidence regarding the safety concerns or contraindications emerges during the course of our trial, the intervention will be discontinued immediately. All newborns will be transitioned back to the prior standard of care without delay.

5.2. Study setting

Due to the unpredictability of neonatal resuscitation, this clinical trial owes to be multicentred to obtain a large number of patients included. The hospitals included will be provided with the personal necessary from both gynaecological and neonatology teams along with a neonatal intensive care unit (NICU), making the immediate follow-up possible.

The hospitals included, should they accept our request for participation, will be:

- Trueta Hospital of Girona
- Vall d'Hebron University Hospital of Barcelona
- Clínic Hospital of Barcelona
- Del Mar Hospital of Barcelona
- Sant Joan de Déu Hospital of Barcelona
- Joan XXIII University Hospital of Tarragona
- Arnau de Vilanova University Hospital of Lleida

These hospitals have been selected because they are equipped with NICUs and provide a broad representation of our region. This selection ensures that the protocol developed during this trial can be effectively extended across Catalonia.

Before the study, all the staff involved will undergo a 5-day training, during which they will be taught neonatal CPR and the use of LifeStart™ Beds, whereas instructed on selection criteria, consent approach and outcome measurements.

Regarding neurodevelopmental follow-up, assessments will be conducted by a paediatric neurologist during neuropediatric outpatient consultations at each hospital when the child reaches 6, 12, 24, and 42 months of corrected age (number of weeks since the date of birth minus number of weeks the newborn was preterm (45)), respectively. Our intervention has demonstrated benefits in previous trials, therefore, this follow-up will not delay the implementation of a protocol in the short term, provided that sufficient data on the main parameters under study is available.

5.3. Study population

The study's target population includes non-vigorous newborns of any gestational age above the limit of viability (23 weeks) born in any hospital participating that require resuscitation in the delivery room.

5.4. Participation criteria

Inclusion criteria

- Newborns born at > 23 weeks of gestation
- Non-vigorous at birth
- Indication of resuscitation according to current guidelines
- Singleton pregnancies
- Adequate prenatal control during pregnancy
- Parental/guardian consent obtained before delivery

Exclusion criteria

- Newborns below the limit of viability (< 23 weeks of gestational age)
- Severe congenital malformations incompatible with life
- Twins, triplets or higher order multiple pregnancies
- Evidence of abruption placenta or cord abnormalities, placenta accreta or percreta, anterior placenta previa, or ruptured uterus
- Parent/guardian decision to withhold consent

Withdrawal criteria

- Parent/guardian decision to withdraw consent after inclusion using the consent withdrawal form (Annex 3)
- Emergence of new contraindications of the procedure during the study
- Patients who develop any exclusion criteria during the study
- Equipment unavailability preventing intact cord management
- Clinical decision by the neonatology team to terminate resuscitation efforts

- Change in cord management or resuscitation strategy due to unforeseen clinical complications during delivery
- Newborns who do not survive labour despite advanced cardiopulmonary resuscitation, which will be considered study losses
- Patients who do not attend follow-up neuropediatric outpatient consultation visits, which will also be considered study losses

All study losses and withdrawals must be documented along with the reasons for them. Data collected prior to the withdrawal will be analysed together with the data from the remaining patients of the study.

5.5. Sampling

The sample size estimation was based on detecting a mean between group difference (Intact cord management vs. Immediate cord clamping) in changes across the assessment points (1 minute, 5 minutes and 10 minutes) higher than 1 point for the overall Apgar score, which was established as the clinically relevant threshold for this evaluation. A standard deviation of 2 was assumed (46).

Using a two-tailed hypothesis, an alpha value of 0.05, and a desired power of 80%, 63 participants per group are required to complete the study during immediate follow-up, as no losses are anticipated during this time. To account for a potential 20% loss during neurodevelopment follow up, we plan to enrol a total of 158 newborns in the study (79 per group).

5.5.1. Sample selection

A convenience-based sampling method will be performed. All pregnant patients (including cisgender women, transgender men, and individuals with intersex variations who retain functional female reproductive organs) admitted for labour at any of the hospitals included, and who do not meet any exclusion criteria, will be approached for consent as soon as possible during the first stage of labour (from the onset of regular uterine contractions that cause cervical dilation to complete dilation of the cervix to 10 centimetres (47)). If they sign the Informed Consent

(Annex 2) after reviewing the Patient Information Document (Annex 1) and having sufficient time to address any concerns, their newborn will be allocated to intervention or control group as soon as they are considered non-vigorous (poor tone, pale skin and lack of breathing in 15 seconds) and need resuscitation efforts.

Newborns whose parents signed the informed consent but end up not needing any support will be excluded from the study sample to avoid selection bias.

If at any point of the study the parents/legal guardians want to withdraw their child, or the newborn exhibits any withdrawal criteria, he/she will be excluded from the study, but data collected prior to this withdrawal will be included in the analysis.

5.5.2. Masking techniques

Parents and caregivers cannot be blinded to the group allocation due to the nature of our intervention. However, data managers and the statistician will be blinded to the group allocation by using coded labels for the intervention and control groups, only decipherable by the main investigators, not involved in data collection.

5.5.3. Estimated recruitment time

Currently, no strategies exist that allow medical teams to predict non-vigorous births, making resuscitation highly unpredictable. Approximately 15% of all newborns require assistance during birth. While this may seem low, out study is multicentric, and with around 10,000 babies born every year in the participating hospitals, the recruitment process will be feasible within 1 year.

5.6. Variables and measurements

5.6.1. Independent variables

- **Intervention group:** Newborns whose cord is left intact during resuscitation manoeuvres.
- **Control group:** Newborns whose cord is clamped before receiving resuscitation manoeuvres.

5.6.2. Dependent variables

MAIN VARIABLE

Apgar score: evaluation method for reporting the status of the newborn immediately after birth and the response of resuscitation if needed. However, it does not determine the need for resuscitation, what steps are necessary or when to use them (48).

The Apgar score will be evaluated by the neonatology team at 1, 5 and 10 minutes of life. There are 5 different signs involved (activity, pulse, grimace, appearance and respiration) which will be evaluated individually and give a total score between 0 points and 10 points (49).

A resume of Apgar scoring system is presented in the next table:

	0 Points	1 Point	2 Points
Activity (Muscle tone)	Limp	Some Flexion	Active, Motion
Pulse (Heart rate)	Absent	< 100 BPM	> 100 BPM
Grimace (Reflex irritability)	No response	Grimace	Cry or active withdrawal
Appearance (Skin colour)	Blue or Pale	Acrocyanotic	Completely pink
Respiration	Absent	Weak cry: hypoventilation	Good, crying

***Table 3. Apgar evaluation adapted from American College of Obstetricians and Gynaecologists (ACOG)* (48).**

Each of the five criteria is scored individually and the total score is calculated by adding the five values obtained (49). A total of 7 points or more in the Apgar score is considered normal.

The total score of each newborn at the standardized times (1-minute, 5-minute and 10-minute Apgar) will be extracted from the labour document and registered as a discrete quantitative measure with a range between 0 and 10 points.

SECONDARY VARIABLES

- **Umbilical cord pH:** blood gas analysis (BGA) of the umbilical cord is an objective evaluation of the newborn acid-basic status; pH ciphers from the umbilical artery have proven to be the best measure of the presence and intensity of fetal acidosis as they reflect the tissular acid-basic status (50).
  The normal value is considered pH 7.15-7.38 in term newborns and 7.14-7.4 in preterm newborns (51).
  The umbilical pH will be measured at 5 and 20 minutes by a neonatology nurse using a 2 ml plastic syringe without heparin and analysed using the Blood Gas Analyzer ABL9 (Radiometer, Copenhagen, Denmark). The measures will be noted in the labour document.
  The results of these measurements will be registered as continuous quantitative with a range of pH from 0 to 14.
- **Blood pressure:** it is the force of blood pushing against the walls of the body's arteries during the heart contraction (52). It will be measured by the neonatology nursing staff during NICU stays with a calibrated non-invasive blood-pressure monitor choosing the appropriate size blood pressure cuff that covers at least 2/3 of length of the upper right arm (if the right arm is unavailable for any reason, the left arm or any of the legs will be appropriate). Measurements will be noted every 4 hours up to the first 72 hours of life.
  The data collected and compared will be the mean arterial pressure (MAP), not the individual measurements of systolic and diastolic blood pressures. The MAP will be calculated with a mathematic formula (Diastolic Pressure + 1/3 (Systolic Pressure – Diastolic Pressure) and recorded as millimetres of mercury (mmHg).
  In connection with haemodynamic failure, it is important to acknowledge that blood pressure is linked to other signs of hypoperfusion, including skin changes (paleness, slow capillary refill and cold extremities), an increased heart rate, neurological changes (irritability, poor appetite…) or oliguria (53).
  In Figure 9 there is a graphic representation of the MAP evolution in newborns between 23 and 43 weeks during the first 72 hours.

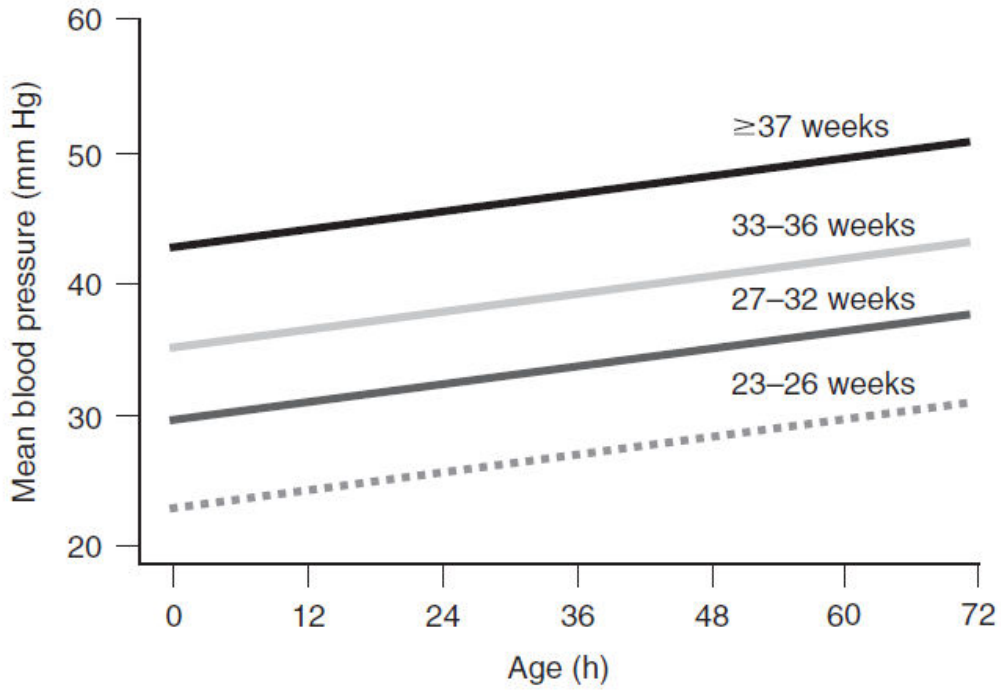

Figure 9. Mean Arterial Pressure in newborns 23-43 weeks (54).

The MAP will be registered as a continuous quantitative measure in mmHg.

- **Septic parameters:** neonatal sepsis refers to an infection involving the bloodstream in infants under 28 days old (23). Neonates with bacteriemia can be asymptomatic, so laboratory test play an important role in diagnosis. Procalcitonin (PCT) and C-reactive protein (CRP) are well known septic parameters that rise in these clinical situations. For its evaluation, a venous blood sample will be taken by the neonatology nursing team first thing in the morning from an umbilical vein catheter with a 4 ml tube without additives (approximately 8:00 am) every 24 hours for the first 7 days of life.

  A capillary gasometry sample taken with a lancet and analysed with a Blood Gas Analyzer ABL 9 will also be considered valid.

  PCT will be measured in ng/ml (considering normal <0,65 ng/ml) and CRP will be measured in µg/ml (considering normal < 5 µg/ml) (55).

  We should make a careful interpretation of PCT values in early-onset sepsis because it has a physiologic elevation in the first 18-36 hours of life (56).

  These parameters will be registered as continuous quantitative, and both the analytic individual results of each day and trend curves will be evaluated.

Trend curves will be useful to determine whether septic parameters increase or decrease during the first 7 days of life, being more suggestive of late-onset sepsis (LOS) if they increase after the first 72 hours of life.

- **Blood count parameters:** the extra blood flow from the placenta to the newborn can be evaluated using parameters such as haemoglobin (Hb) and haematocrit (Ht). Normal ranges or these parameters differ between the gestational ages, and preterm newborns tend to have lower concentrations than term newborns (57).
    - **Haemoglobin:** normal range is 12-18 g/dL in preterm newborns and 14-22 g/dL in term newborns.
    - **Haematocrit:** normal range is 35-55% in preterm newborns and 40-65% in term newborns.

  These parameters will be monitored every 24 hours for the first 7 days of life by the neonatology nursing team, taking a blood sample from the umbilical vein of the newborn first thing in the morning (approximately 8:00 am) using a 4 ml EDTA tube. A capillary gasometry sample taken with a lancet and analysed with a Blood Gas Analyzer ABL 9 will also be considered valid.

  The measures will be registered as continuous quantitative, and the analytic individual results of each day will be analysed.

- **Respiratory distress syndrome (RDS):** it is the most common cause of respiratory distress after delivery associated with a deficiency of surfactant. Chest radiography and arterial blood gas analysis must be performed in any non-specific respiratory symptoms (tachypnoea, nasal flaring, grunting, retractions, cyanosis and decreased air entry on auscultation). To diagnose respiratory distress syndrome, the chest radiography findings can include homogeneous lung decrease with diffuse atelectasis (ground-glass reticulo-granular appearance with air bronchograms and low lung volumes); while blood analysis may show hypoxemia and hypercapnia, metabolic acidosis or even lactic acidemia in worse presentations (58).

  Based on the described clinical, radiological and analytical criteria, any paediatrician from the neonatology team that diagnoses respiratory distress syndrome must include it in the clinical record.

This parameter will be registered as dichotomic nominal qualitative and noted as “yes” or “no” before discharge.

- **Intraventricular haemorrhage (IVH):** it is one of the main neurological complications of preterm newborns. An intracranial ultrasound doppler screening must be performed in all neonates less than 34 weeks between 7 and 10 days of life, repeating screening at 4-6 weeks of age and 36 weeks of corrected gestational age or before hospital discharge. In case of worsening neurological status, a repeat intracranial ultrasound should be performed, or a first ultrasound if one has not been carried out previously (59).

  It is important to clarify that intraventricular haemorrhage incidence is inversely proportional to gestational age; the more premature the newborn, the higher risk of developing intraventricular haemorrhage there is.

  Based on radiological findings (germinal matrix bleeding, blood inside or dilatation of the ventricles or hydrocephaly) (60), a neonatologist can diagnose IVH, and must include its finding in the clinical record.

  Once the diagnosis of IVH is made, it must be classified in degrees (59):

  - *Grade I* – haemorrhage limited to Germinal matrix
  - *Grade II* – IVH without ventricular dilatation
  - *Grade III* - IVH with ventricular dilatation occupying > 50% of the ventricle
  - *Grade IV* – IVH with intraparenchymal haemorrhage

  Grades I and II are referred as “mild IVH”, whereas grades III and IV are referred as “severe IVH” (59).

  This parameter will be registered as polytomous nominal qualitative and noted as “No IVH”, “Mild IVH” and “Severe IVH” before discharge.

- **Necrotizing enterocolitis (NEC):** inflammation of the intestine leading to bacterial invasion causing cellular damage and death, resulting in necrosis of the colon and intestine. If clinical suspicion arises (abdominal distension and tenderness, visible intestine loops, deceased bowel sounds, palpable abdominal mass and erythema of the abdominal wall) abdominal plain film series including anterior-posterior and left lateral decubitus X-rays must be

performed. Findings of dilated loops of bowel, pneumatosis intestinalis and portal venous air are diagnostic for necrotizing enterocolitis (61).

If a neonatologist diagnoses any newborn with NEC, they must note their findings in the clinical record.

This parameter will be registered as polytomous nominal qualitative as "yes" or "no" before discharge.

- **Late-onset sepsis (LOS):** neonatal bloodstream infection occurring after 72 hours of life, frequently caused by pathogens from the surrounding environment after delivery. When septic blood parameters (PCT and CRP) increase after 72 hours of life, a blood culture from the umbilical vein should be immediately obtained (at least 1ml of blood). Additionally, urine cultures must be considered. If a blood culture is positive or the clinical presentation suggest central nervous system involvement, a lumbar puncture with cerebrospinal fluid (CSF) analysis and culture should be performed (23).

  If a neonatologist diagnoses any newborn with LOS, they must note their findings in the clinical record.

  This parameter will be registered as dichotomic nominal qualitative as "yes" or "no" before discharge.

- **Survival:** defined as the absence of death after birth. It's a measurement of the health status the day after birth and will be documented through the clinical records within the first 12-36 hours of life.

  This parameter is a dichotomic nominal qualitative variable and will be registered as "alive" or "deceased".

- **Neurodevelopment:** complex process where the neurons extend and form synaptic connections to define an individual's neurocircuitry (62). To evaluate neurodevelopment, the Ages and Stages Questionnaire, Third Edition (ASQ-3), presented in Annexes 4-7 will be performed at 6, 12, 24 and 42 months of corrected age (18). The corrected age will be calculated subtracting the number of weeks the baby was preterm (40 – gestational age at birth) from the baby's actual age (number of weeks since birth) (45).

  The ASQ-3 comprises 30 questions covering 5 developmental domains: communication, gross motor skills, fine motor skills, problem-solving, and

personal-social skills. These questions are based on milestones to be achieved between birth and 5 years and 6 months. The questionnaire can be completed by an evaluator or a self-report by parents with a reliability of 93% (18). In our study, parents will answer the questionnaire guided by a paediatric neurologist in the outpatient neuropediatric consultations.

Since the ASQ-3 provides a quantitative result, a comparison of the acquisition of a greater or lesser number of skills in the assessed areas at different checkpoints between intervention and control groups is feasible, making it highly valuable for our study.

This parameter will be registered as a discrete quantitative result for domain-specific scores. If any questions from the "OVERALL" section have an altered response, this will also be noted in the data collection sheet.

5.6.3. Covariables

Randomization will be performed to avoid confounding factors to be differentially distributed between intervention and control groups, but they must be considered.

- **Newborn factors:**
    - **Gestational age:** preterm newborns may have different clinical outcomes than term newborns due to their general immaturity in several systems and organs. Also, the resuscitation algorithms are different for newborns born before 32 weeks of gestational age.

      Gestational age at birth will be extracted from the clinical record and recorded as a continuous quantitative variable in weeks.
    - **Fetal growth:** restricted fetal growth has been associated with higher perinatal morbimortality. Small for gestational age (SGA) is defined as estimated fetal or birth weight below the 10th percentile, whereas intrauterine growth restriction (IUGR) presents additional abnormalities (pathological doppler sonography, oligohydramnios, estimated weight below 3rd percentile or lack of growth) (63).

      On the other hand, large for gestational age (LGA) is defined as estimated fetal or birth weight above the 90th percentile (64).

Finally, adequate for gestational age (AGA) babies are those in between the 10th and the 90th percentiles.

Any of these conditions can be found during routinary gestational ultrasounds performed by a midwife or a gynaecologist.

The information on fetal growth will be extracted from the clinical record. This variable will be recorded as polytomous nominal qualitative, referenced as Intrauterine Growth Restriction (IUGR), Small for gestational age (SGA), Adequate for gestational age (AGA) or Large for gestational age (LGA).

- **Congenital anomalies or comorbidities:** minor congenital anomalies or other comorbidities (specially heart or lung defects) may compromise the effectivities of resuscitation.

  The presence of any minor congenital defect or comorbidity will be detected during routinary pregnancy follow-up ultrasounds and noted in the clinical record. It will be recorded as a dichotomic nominal qualitative variables ("yes" or "no").
- **Antenatal corticosteroid administration:** corticosteroids are indicated in 24+0 to 33+6 weeks of pregnancy. They accelerate pulmonary maturation and reduce the incidence of RDS (65). Antenatal corticosteroid administration will be documented in the clinical record if threatened premature labour occurs. This variable will be recorded as dichotomic nominal qualitative ("yes" or "no").
- **Antenatal neuroprotection administration:** magnesium sulphate is indicated in threatened preterm delivery before 32 weeks of gestational age (66). Magnesium sulphate administration will be documented in the clinical record if threatened premature labour occurs. This variable will be recorded a dichotomic nominal qualitative ("yes" or "no").
- **Early-onset sepsis (EOS):** neonatal bloodstream infection occurring before 72 hours of life, frequently caused by pathogens from the female genitourinary system, also called vertical sepsis. When septic blood parameters (PCT and CRP) increase before 72 hours of life, a

blood culture from the umbilical vein should be immediately obtained (at least 1ml of blood). If the blood culture is positive or the clinical presentation suggest central nervous system involvement, a lumbar puncture with cerebrospinal fluid (CSF) analysis and culture should be performed (23). If a neonatologist diagnoses any newborn with EOS, they must note their findings in the clinical record.

This parameter will be registered as dichotomic nominal qualitative and noted as “yes” or “no” before discharge.

- **Pregnancy factors:**
    - **Rh sensibilization:** if there is Rh incompatibility (Rh-negative parent with a Rh-positive baby), sensibilization can occur during labour or if their bloods mix during pregnancy. This can cause polyhydramnios, jaundice, hypotonia and lethargy on the fetus due to blood cell haemolysis. To prevent sensibilization, immunoglobulins (RhoGAM) can be used in Rh-negative parents with Rh-positive babies (67).

      To detect sensibilization, indirect Coombs test must be performed in every pregnant patient and its result is attached to the clinical record. If the test is positive, sensibilization has occurred, and vice versa.

      This variable will be registered as dichotomic nominal qualitative (“positive” or “negative”) before delivery.
    - **Diabetes:** chronic, metabolic disease characterized by elevated levels of blood glucose, which leads over time to serious damage to the heart, blood vessels, eyes, kidneys or nerves (68). Pregestational diabetes (Type 1 or 2) or gestational diabetes can be present, and both can lead to hypoglycemia, macrosomia, IUGR, prematurity, malformations, hematological issues or others in the newborn (69).

      The presence of both pregestational and gestational diabetes will be noted in the labour document. This variable will be registered as dichotomic nominal qualitative (“yes” or “no”) before delivery.
    - **Hypertension:** condition in which the blood vessels have persistently raised pressure (70). Gestational hypertension (developed during pregnancy), chronic hypertension (pregestational) and other more

serious gestational hypertension conditions like preeclampsia, eclampsia and HELLP syndrome can be developed. All of these presentations can affect the newborn in different ways like prematurity or low birth weight (71).

The presence of both any hypertensive status will be noted in the labour document. This variable will be registered as dichotomic nominal qualitative ("yes" or "no") before delivery.

- **Infection**: any acute or chronical infection can affect the newborn in different ways altering the needs for resuscitation. The presence of chorioamnionitis, intrapartum fever, positivity of streptococcus agalactiae or positive serologies for other microorganisms (syphilis, human immunodeficiency virus, rubeola or hepatitis) will be noted in the labour document.

  This variable will be registered as dichotomic nominal qualitative ("yes" or "no") before delivery.

- **Mode of delivery:** vaginal labour, instrumented labour or c-section have potential different outcomes for the newborn and its need for resuscitation manoeuvres.

  The mode of delivery will be noted in the labour document.

  This variable will be registered as polytomous nominal qualitative (vaginal / instrumented / c-section) after delivery.

- **Duration of labour:** time elapsed from the onset of regular uterine contractions accompanied by a progressive cervical dilation to the complete delivery of the newborn (47). Total length of labour will be measured in hours and minutes and extracted from the labour document. This parameter will be registered as a continuous quantitative variable and measured in hours and minutes.

- **Delivery complications:** the presence of placental anomalies, uterine rupture or cord around the neck determine different outcomes for the newborn and its need for resuscitation, also potentially varying the group allocation. The presence of any will be extracted from the labour document or clinical record.

This parameter will be registered as dichotomic nominal qualitative ("yes" or "no") after delivery.

- **Type of membrane rupture:** we can classify it in spontaneous, premature or artificial. Especially premature ruptures can have different outcomes for the newborns, in particular premature ruptures longer than 18 hours also have a higher risk of vertical sepsis (72). This information will be noted in the labour document.

  This variable will be registered as polytomous nominal qualitative (spontaneous / premature / artificial) after delivery.

- **Resuscitation factors:**
  - **Time to establish effective ventilation:** whenever a non-vigorous newborn is delivered, time between birth and the recuperation of spontaneous breathing must be measured in minutes and noted in the clinical record after resuscitation. This parameter will be registered as continuous quantitative and measured in minutes.
  - **Use of medications during resuscitation:** the use of any drugs or volume expanders like epinephrine, saline solutions, blood, or others during resuscitation manoeuvres will be noted in the clinical record.

    This variable will be registered as dichotomic nominal qualitative ("yes" or "no") after resuscitation.

Table 4. Outcome summary.

Variable	Description	Data source	Measures	Time points
Apgar score	Discrete quantitative	Labour document	Neonatologist (0-10 points)	1, 5 and 10 minutes
Umbilical cord pH	Continuous quantitative	Labour document	Blood Gas Analyzer ABL 9 (pH 0-14)	5 and 20 minutes
Blood pressure	Continuous quantitative	Neonatology nurse's records	Calibrated Blood-pressure monitor (MAP in mmHg)	Every 4 hours for 3 days
Septic parameters	Continuous quantitative	Blood samples	PCT (ng/ml) and CRP (µg/ml) values	Every 24 hours for 7 days

Blood count parameters	Continuous quantitative	Blood samples	Hb (g/dL) and Ht (%)	Every 24 hours for 7 days
Respiratory distress syndrome	Dichotomic nominal qualitative	Clinical record	Yes/No	Before discharge
Intraventricular haemorrhage	Polytomous nominal qualitative	Clinical record	No IVH / Mild IVH / Severe IVH	Before discharge
Necrotizing enterocolitis	Dichotomic nominal qualitative	Clinical record	Yes/No	Before discharge
Late-onset sepsis	Dichotomic nominal qualitative	Clinical record	Yes/No	Before discharge
Survival	Dichotomic nominal qualitative	Clinical record	Alive/Deceased	12-36 hours after birth
Neurodevelopment	Discrete quantitative	ASQ-3	Domain-specific scores (0-60 points)	6, 12, 24 and 42 months
Gestational age	Continuous quantitative	Clinical record	Weeks	At birth
Fetal growth	Polytomous nominal qualitative	Clinical record	IUGR / SGA / AGA / LGA	At birth
Congenital anomalies	Dichotomic nominal qualitative	Clinical record	Yes/No	At birth
Antenatal corticosteroid administration	Dichotomic nominal qualitative	Clinical record	Yes/No	At birth
Antenatal neuroprotection administration	Dichotomic nominal qualitative	Clinical record	Yes/No	At birth
Early-onset sepsis	Dichotomic nominal qualitative	Clinical record	Yes/No	Before discharge

Rh sensibilization	Dichotomic nominal qualitative	Labour document	Indirect Coombs (Positive/Negative)	Before delivery
Diabetes	Dichotomic nominal qualitative	Labour document	Yes/No	Before delivery
Hypertension	Dichotomic nominal qualitative	Labour document	Yes/No	Before delivery
Infection	Dichotomic nominal qualitative	Labour document	Yes/No	Before delivery
Mode of delivery	Polytomous nominal qualitative	Labour document	Vaginal / Instrumented / C-section	After delivery
Duration of labour	Continuous quantitative	Labour document	Hours and minutes	After labour
Delivery complications	Dichotomic nominal qualitative	Labour document	Yes/No	After labour
Type of membrane rupture	Polytomous nominal qualitative	Labour document	Spontaneous / Premature / Artificial	After labour
Time to establish effective ventilation	Continuous quantitative	Clinical record	Minutes	After resuscitation
Use of medications during resuscitation	Dichotomic nominal qualitative	Clinical record	Yes/No	After resuscitation

5.7. Study intervention

5.7.1. Randomization

All newborns meeting inclusion criteria without meeting exclusion or withdrawal criteria will be included in the study. Randomization will ensure that the different covariables are equally distributed among both groups, making them comparable for the different outcomes.

Given the variability in newborns, a stratified randomization based on gestational age and fetal growth would be the appropriate method to minimize imbalance across these factors. The stratums would be elaborated as following:

- **Stratum 1:** preterm, adequate for gestational age (< 37 weeks, p10-p90)
- **Stratum 2:** preterm, small for gestational age (< 37 weeks, < p10)
- **Stratum 3:** preterm, large for gestational age (< 37 weeks, > p90)
- **Stratum 4:** preterm, intrauterine growth restriction (< 37 weeks, IUGR)
- **Stratum 5:** term, adequate for gestational age (> 37 weeks, p10-p90)
- **Stratum 6:** term, small for gestational age (> 37 weeks, < p10)
- **Stratum 7:** term, large for gestational age (> 37 weeks, > p90)
- **Stratum 8:** term, intrauterine growth restriction (< 37 weeks, IUGR)

To maintain equal group sizes within each stratum, block randomization would be the most adequate strategy to assign the intervention, ensuring similar distribution of confounding factors, making the groups comparable.

A computer program will be used to perform it, using variable random permutated block sizes of 4-8 for each stratum to avoid predictability in group assignation.

5.7.2. Intervention

Once randomization is performed, a trained neonatology team will carry out neonatal resuscitation, either maintaining the umbilical cord unclamped or following standard care (immediate cord clamping), according to the group assignation in a 1:1 ratio.

- **Intervention group:** for intact cord management to be maintained during all the stages of neonatal resuscitation, LifeStart™ Bed will be used, complemented with two gas cylinders, a suction system, a Neopuff resuscitator with end-tidal CO2 detector, an oxygen blender, a flowmeter and a saturator. The LifeStart™ Bed will be positioned over the pregnant patient to avoid stretching the cord, and the newborn will be positioned in the thermic mattress to maintain heat.

The phases of resuscitation will be performed as standard care procedures, but the cord will be left intact during the totality of the resuscitation efforts.

- **Control group:** the standard care of current practice will be performed. As soon as the newborn is in need for assistance from the neonatology team the cord will be immediately clamped, and the newborn will be transferred to a conventional resuscitation platform, equipped with at least a radiant heater, a Neopuff resuscitator with a T-piece, an Apgar clock and a saturator.
  The different phases of CPR will be performed following the standard algorithms from the SENeo (Figures 4 and 5), with the cord already clamped.

	Intervention group: Intact Cord Management	**Control group: Immediate Cord Clamping**
Cord management	Intact cord maintained throughout resuscitation	Cord clamped immediately upon need for resuscitation
Resuscitation platform	LifeStart™ Bed	Conventional resuscitation platform
Location	Newborn remains with the parent on LifeStart™ Bed to avoid cord stretching	Newborn transferred to the resuscitation platform
Resuscitation approach	Standard CPR procedures (SENeo algorithms) performed with intact cord	Standard CPR procedures (SENeo algorithms) performed after cord clamping

Table 5. Key aspects of the study intervention.

5.7.3. Follow-up

There will be two lines of follow-up:

- **Immediate follow-up:** it will be performed during neonatal intensive care unit (NICU) stay of the newborn. Throughout this time, the information recorded will be blood pressure, septic parameters, blood count parameters, respiratory distress syndrome, intraventricular haemorrhage, necrotizing enterocolitis, early/late-onset sepsis and survival.
- **Neurodevelopment follow-up:** the parents/legal guardians will be asked to attend neuropediatric consultations along with their children at 6, 12, 24 and

42 months of corrected age to perform the ASQ-3 questionnaires and evaluate neurodevelopment. These appointments will be programmed through the standard citation system and two reminders will be done (prior week and prior day) to avoid follow-up losses and reprogramme the appointment promptly if attendance is not possible.

This 4-year follow-up will not prevent the development of a standardized protocol to implement intact cord management during neonatal resuscitation in a short term, provided that the initial statistical analysis confirms our main hypothesis, and the intervention proves to be safe.

The parents/legal guardians will be asked to contact the investigator at any time if questions or complications arise during the complete follow-up period.

5.7.4. Data analysis

A professional statistician, independent from the intervention and data collection and blinded for the group assignation, will analyse the initial data when the necessary sample size has been achieved. Once neurodevelopment follow-up has been completed for the totality of the sample, these data will be also analysed.

When the data analysis is completed, the main investigators and co-investigators will evaluate the results and deliver their conclusions.

5.8. Data collection

The data collection will be carried out by at least two different professionals through a standardised data collection sheet (Annex 8). The first professional will be responsible for collecting complications and initial clinical outcomes, whereas the second one will be responsible for collecting the neurodevelopmental outcomes.

This data compilation will be done in standardized times: after delivery, after hospital discharge and during the neuropediatric outpatient consultations.

5.8.1. After delivery

Once the newborn is delivered and our intervention is performed, the responsible professional (one neonatologist from each hospital) will collect all the potential covariables (pregnancy factors, newborn factors (except from early-onset sepsis) and resuscitation factors), along with Apgar scores and umbilical cord pH at standardized times.

This information will be registered in the data collection sheet from Annex 8.

5.8.2. At hospital discharge

When the hospital discharge occurs, the second assessment must be performed. Either the same neonatologist or a new one can collect the data from the NICU stay.

This information includes blood pressure, septic parameters, blood count parameters, respiratory distress syndrome, intraventricular haemorrhage, necrotizing enterocolitis, early/late-onset sepsis and survival.

All this information will be registered in the data collection sheet from Annex 8.

5.8.3. During neurologic consultations

During the neurodevelopment follow up, a new professional, this time a paediatric neurologist, will collect the information from the Ages and Stages Questionnaires (3rd edition), filled out by the parents at 6, 12, 24 and 42 months of corrected gestational age.

The result from each individual questionnaire will be added to the data collection sheet from Annex 8.

5.9. Flow diagram

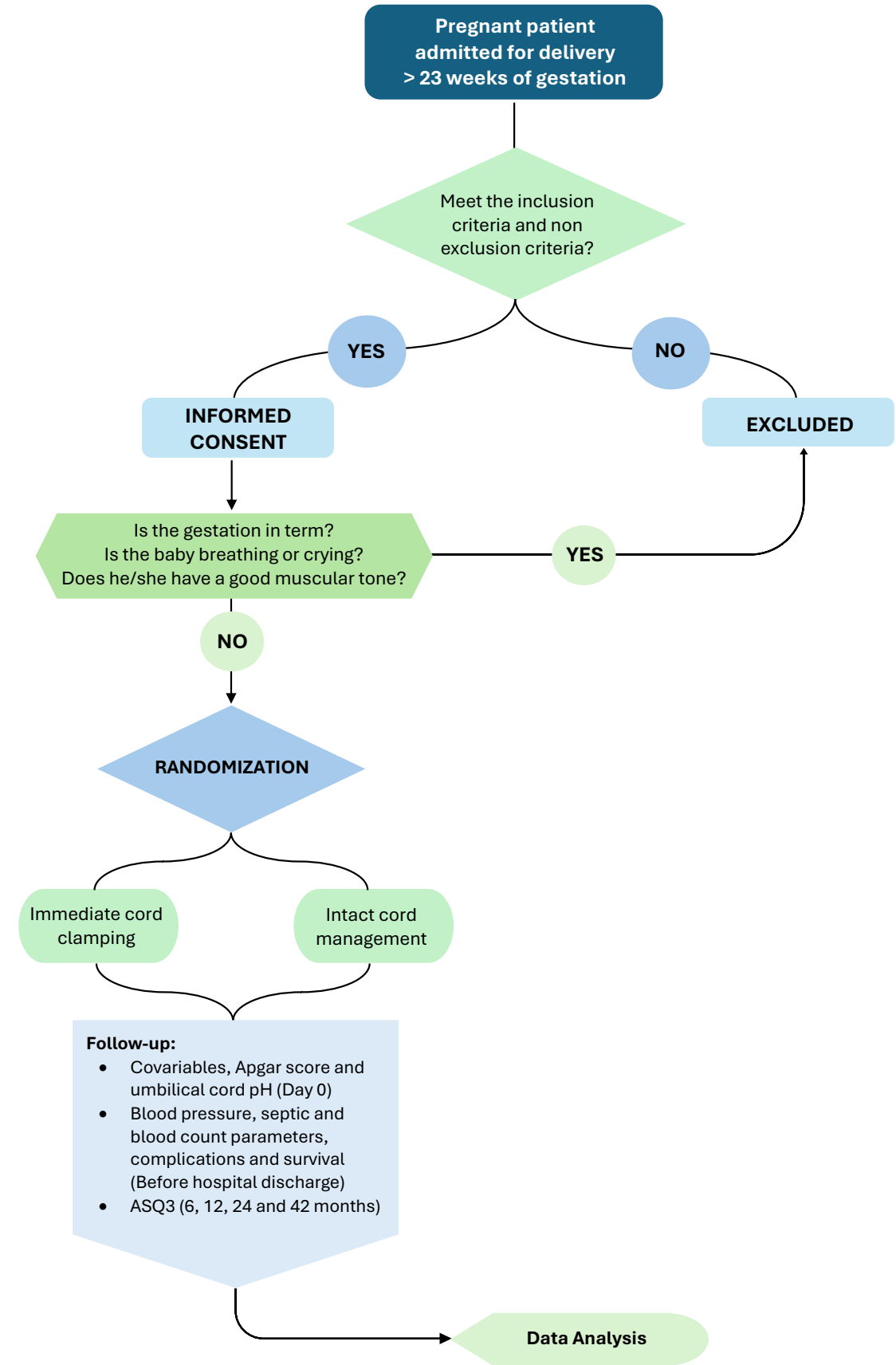

Figure 10. Study design flowchart.

6. STATISTICAL ANALYSIS

The statistical analysis will be carried out by a professional statistician. Patients will be analysed according to the treatment group to which they were randomized, regardless of the treatment that they end up receiving (intention-to-treat analysis).

We will establish a 95% confidence interval and less than 5% of error probability will be considered statistically significant (p value < 0,05).

6.1. Descriptive analysis

With the intention of summarizing baseline characteristics and outcomes, a descriptive analysis needs to be carried out.

Quantitative variables, including dependent variables (e.g., Apgar scores, umbilical cord pH) and covariates (e.g., time to establish effective ventilation, duration of labour) will be presented as means with standard deviations for normal distribution, or medians with interquartile ranges for skewed distribution.

Qualitative variables, including both dependent variables (e.g., respiratory distress syndrome, survival), independent variables (intact cord management) and covariates (e.g., mode of delivery, type of membrane rupture) will be summarized as frequencies (proportions and percentages).

All these analyses will be stratified according to control and intervention group. Additional stratification will be done for the covariates (gestational age and fetal growth have already been stratified in randomization).

6.2. Bivariate analysis

Bivariate analyses will be performed to compare outcomes between the two groups (intact cord management vs. early cord clamping).

Outcome quantitative variables are repeated measures. The discrete variables, specifically Apgar scores and neurodevelopment, will be compared using the Friedman test. For continuous outcomes like umbilical cord pH, blood pressure, septic parameters and blood count parameters, repeated measures ANOVA will be used, adjusting for sphericity violations using Greenhouse-Geisser correction if necessary. These statistical tests account for within-subject correlations.

For the categorical variables (e.g., respiratory distress syndrome, intraventricular hemorrhage, necrotizing enterocolitis or late onset sepsis), Chi-Square tests or Fisher's exact tests will be employed.

Finally, for time-to-event outcomes like survival, Kaplan-Meier curve/log rank test will be applied.

6.3. Multivariate analysis

Multivariate analyses will be made to adjust for potential confounders and prevent the groups from not being comparable.

On the one hand, logistic regression models will be used for binary outcomes (e.g., necrotizing enterocolitis, late-onset sepsis), incorporating covariates to adjust for confounding factors. On the other hand, multinominal logistic regression models will be used for the polytomous outcomes (e.g., intraventricular haemorrhage).

Mixed-effects linear regression models will be used for continuous outcomes (e.g., Apgar scores, blood pressure, neurodevelopment), incorporating fixed effects for group assignment and covariates, allowing these models to account for repeated measures and within-subject correlations.

Finally, for time-to-event outcomes like survival, Cox proportional hazards models adjusted for covariates to control confusion will be applied.

All variables with $p \leq 0.100$ in the univariate analyses will be included in the multivariate analyses. The IBM Statistical Package for Social Sciences (SPSS) software version 30.0 will be used to perform the analysis.

7. ETHICAL AND LEGAL CONSIDERATIONS

When conducting a clinical trial, several ethical and legal considerations must be addressed to ensure compliance with both local and international standards.

7.1. Ethical principles

Our clinical trial will primarily adhere to the Helsinki Declaration of Ethical Principles for Medical Research Involving Human Subjects (World Medical Association, last revision October 2024), which outlines the ethical principles for medical human research. This includes ensuring informed consent, maintaining patient confidentiality, and minimizing harm. As this clinical trial involves children, informed consent must be obtained from their parents or legal guardians. Aligning with these ethical principles, the right to withdraw at any time will be granted.

We also uphold Principles of Biomedical Ethics from Beauchamp and Childress, foundation to the biomedical ethical practices. The four principles are:

- **Autonomy:** parents or legal guardians will be responsible for making decisions regarding their children involvement in the trial. It is essential to ensure they are fully informed about the potential risks and benefits of the procedure, the trial's purpose and the option to withdraw at any time.
  This principle will be upheld by the patient information, informed consent and withdrawal documents.
- **Beneficence:** refers to maximizing the potential benefits for the participants and minimizing risks. Our intervention has been associated with improved neonatal outcomes, supported by solid scientific evidence. The study results and implementation of our intervention will benefit not only trial patients, but also any newborns requiring resuscitation in the delivery room.
  A valid scientific question, proper study justification, and the appropriate study design will maximize benefits.

- **Non-maleficence:** mandates that the trial should cause no harm to the participants. Potential adverse effects will be monitored and minimized. The intervention will be administered by trained professionals from each hospitals' neonatology teams. The benefits of our intervention clearly outweigh the risks, and any patients who could result harmed in any way have been accounted for in the exclusion or withdrawal criteria.
- **Justice:** ensures a fair distribution of benefits and burdens among all patients. Our trial design includes a diverse, unbiased population to ensure representativity and generalizability of results. The inclusion and exclusion criteria have been clearly defined to prevent any unjustified exclusions. Any adverse effects or unexpected results will be managed equitably to avoid biases between groups. And finally, results will be published transparently and the benefits from our intervention will be extended to all the population.

The study will be summited to the "Comité de Ética de Inverstigación Clínica" (CEIC) of the main investigation center, Trueta Hospital of Girona. Submission to the respective CEICs of the participating centers will be optional. Approval from the Hospital Trueta CEIC will be mandatory to conduct this trial; any necessary adjustments recommended will be made to secure their authorization.

7.2. Legal principles

Our trial will comply with the "European Union Clinical Trials Regulation (EU CTR) No 536/2014", ensuring the protection of clinical participants, reliability of the data, and transparency of trial information across the European Union (EU).

Locally, this study has been developed in accordance with the Spanish legislation "Ley 14/2007, de 3 de julio, de Investigación biomédica".

Due to the use of a sanitary product (LifeStart™ Bed), our clinical trial will also adhere to the following legislation:

- "Ley 29/2006, de 26 de julio, de garantías y uso racional de los medicamentos y productos sanitarios"

- “Real Decreto 1090/2015, de 4 de diciembre, por el que se regulan los ensayos clínicos con medicamentos, los comités de ética de la investigación con medicamentos y el registro español de estudios clínicos”.
- “Real Decreto Legislativo 1/2015, de 24 de julio, por el que se aprueba el texto refundido de la Ley de Garantías y uso racional de los medicamentos y productos sanitarios”.

Privacy and confidentiality will be preserved. All patient information will be anonymized using coded numbers, and then it will be stored in a database only accessible to the research team, complying with the current legislation:

- “Reglamento (UE) No 2016/679 del Parlamento Europeo y del Consejo, de 27 de abril de 2016, relativo a la protección de las personas físicas en lo que respecta al tratamiento de datos personales y a la libre circulación de estos datos”.
- “Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales (LOPD-GDD), en especial su Disposición Adicional 17.2”.

Autonomy will also be protected according to the “Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica”.

Investigators and coordinators will respect the Good Clinical Practice (CGP) and declare any personal conflicts of interest related to any aspect of this research. Coordinators will manage all the legal aspects of this trial.

The project will be registered at the “Registro Español de Estudios Clínicos (REec)” before its beginning. Once data is analyzed and results are obtained, they will be published transparently and disclosed to both health and non-health related public in scientific papers and presented at the next National Neonatology Congress.

8. STRENGTHS AND LIMITATIONS

We believe that this clinical trial will provide sufficient evidence to support the development of a local protocol. Our study design is robust, and randomization minimizes selection bias, ensures comparable groups and establishes causality. Moreover, the statistical analysis plan ensures the control of potential confounding factors. Finally, the inclusion of different hospitals increases its generalizability.

Even having several strengths, out study has limitations we should not disregard.

Coordinating different centers can be challenging, leading to logistical difficulties when applying the protocol, assessing clinical outcomes and developing follow-up. Variability between hospitals can lead to inter-observer biases, information biases, and detection biases. We will prevent them by developing a standardized protocol and training the professionals involved. Follow-up meetings with the hospital coordinators will be performed to solve any difficulties that arise during the trial.

Blinding of the intervention is impossible in our trial due to its nature, as it has already been stated, increasing the risk of detection bias. However, data managers and the statistician will be blinded to the group allocation, minimizing this bias.

Ethical considerations must be also addressed for this trial, as it involves newborns in need for resuscitation maneuvers, which is a critical time-sensitive procedure. As explained in Section 7, ethical principles will be respected, and our intervention will not delay the proper care for all newborns. Furthermore, informed consent in emergency settings can be challenging; in our study, all pregnant patients admitted to the delivery room will be addressed for consent during the first stage of labor, preventing losses and respecting the parental right to decide for their newborn care.

This study is presented as a prospective clinical trial, making withdrawals possible. We have anticipated a 20% drop-out rate during follow-up in our sample size estimation. Additionally, several reminders will be made to prevent any absence during consultations, encouraging participation.

9. WORKING PLAN AND CHRONOGRAM

9.1. Research team members

The study will be conducted by the following team:

- **Principal investigators (PI):** two members from the neonatology team of Trueta Hospital will be the research team responsible for developing the protocol, supervising the intervention, obtaining conclusions and publishing the results. They will be primarily responsible for presenting the project to the "Comité de Ética de Investigación Clínica" (CEIC) and making decisions.
- **General coordinator (GC):** the head of the neonatology team from Trueta Hospital will coordinate all the clinical coordinators from each hospital, develop training prior to the study, oversee data collection during the study and present the collected information to the statistician.
- **Hospital coordinators (HC):** one for each participating hospital. It will be a different member from the neonatology team, who will collect the data and ensure the proper execution of procedures within their respective centre.
- **Co-investigators (CI):** a neonatology team formed by at least one neonatologist and one neonatal intensive care unit (NICU) nurse from every hospital will oversee the recruiting process and randomly assign and perform the intervention in each newborn. Furthermore, they will be responsible for the initial assessment in the delivery room.
- **Data managers (DM):** responsible for collecting the data in each phase of the study and creating a database to perform the statistical analysis.
- **Statistician (ST):** independent statistician that performs the different statistical analysis of the study.
- **Collaborators (CB):** NICU staff, gynaecologic teams and paediatric teams (especially neuropediatric teams from each hospital).

9.2. Study stages

Recruitment of patients will last 12 months, with a follow-up period of 42 months for each patient. This clinical trial is expected to last 6 years and will be divided in the following stages:

Stage 0: Study design and ethical approval (November 2024 – April 2025)

- **Elaboration of the protocol:** the main investigators will conduct bibliographic research to provide a background and to identify the objectives, hypothesis, and methodology of the study. The latest evidence in cord management during neonatal resuscitation has been widely reviewed to elaborate each section of this document.
- **Ethical evaluation and study approval:** the protocol will be reviewed by the CEIC of Trueta Hospital for its approval. Any proposed modifications will be considered and incorporated.
- **Selection of participating hospitals and coordinators:** the research team will send a proposal to each selected hospital to invite their participation, including a copy of the protocol for their review. The general coordinator and clinical coordinators from each centre will also be approached to secure their collaboration.

Stage 1: Study coordination (May 2025 - June 2025)

- **Research team meeting:** investigators and coordinators will meet; the study will be appropriately explained, including all phases and tasks, and any questions will be answered to ensure adequate comprehension of the protocol and collaboration between each participating centre.

  Clinical coordinators and principal investigators will then meet online every 3 months to ensure the correct implementation of the protocol.
- **Personnel recruitment:** paediatricians and nurses from the respective neonatology teams of each hospital will be asked to participate in the study. At least two members from each team will be necessary to perform the

intervention, but ideally four professionals in each hospital. The data managers will be at least one neonatologist and a paediatric neurologist from each centre. A qualified independent statistician will be hired to complete the statistical analysis.

- **Training sessions:** the neonatology teams involved will undergo a 5-day training, during which they will be taught neonatal resuscitation and the use of LifeStart™ Bed, whereas instructed on selection criteria, randomization, consent approach and outcome measurements. Co-investigators and coordinators will also participate in this training sessions, receiving information about the legal aspects and their respective specific tasks.
- **Database creation:** the data managers will elaborate a database to include all the information obtained from the data collection process.

Stage 2: Recruitment, intervention and data collection (July 2025 - June 2030)

- **Sample recruitment:** patients will be recruited based on a convenience-based sampling method. All of those who meet the inclusion criteria, do not meet any exclusion criteria, and whose parents/legal guardians provide informed consent, will be included in the trial. The patient recruitment period is anticipated to last 12 months.
- **Intervention and follow-up:** depending on the group assignment, the newborn will be treated with usual care (immediate cord clamping) or intact cord management during neonatal resuscitation in the delivery room. Immediate follow-up will be done during the NICU stay of each newborn included in the study and will finish at their hospital discharge. Neurodevelopmental follow-up will continue for a total of 42 months by attending paediatric neurology outpatient consultations.
- **Data collection:** initial data will be collected by one data manager, after performing the intervention (Covariables, Apgar score and umbilical cord pH). The rest of the data from the NICU stay and the neurodevelopment follow-up will be collected by two different data managers. Clinical coordinators will supervise the data collection.

Stage 3: Data analysis and Results interpretation (July 2030 – September 2030)

- **Statistical analysis**: the analysis of the information existent in the database will be realized by the independent statistician. Initial data analysis will be performed after the immediate follow-up (approximately from July to September 2026), to provide a basis for the elaboration of an agreed-upon protocol for the implementation of our study intervention.
- **Interpretation and conclusion:** data will be discussed and interpretated by the principal investigators to arrive to the conclusions. If initial data confirms the hypothesis of our study, it will set the basis for an agreed-upon protocol.

Stage 4: Edition and publication (October 2030 – November 2030)

- **Paper redaction:** the principal investigators will write an article with a detailed explanation of the protocol, the results and the conclusions obtained. It will include title, abstract, introduction, methodology, results, conclusion and discussion.
- **Publication and dissemination:** the paper will be published in scientific papers and presented at the first available SENeo ("Sociedad Española de Neonatología") National Neonatology Congress.

9.3. Chronogram

ACTIVITY	STAFF	YEARS AND MONTHS																																							
		2024		2025												2026												2027	2028	2029	2030									
		N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J-D	J-D	J-D	J-J	J	A	S	O	N						
Stage 0: Study design and Ethical approval																																									
Protocol elaboration	PI																																								
CEIC approval	PI																																								
Selection of hospitals and coordinators	PI																																								
Stage 1: Study coordination																																									
Research team meeting	PI, GC, HC, CI, DM, CB																																								
Personnel recruitment	GC, HC																																								
Training sessions	GC, HC, CI, CB, DM																																								
Database creation	DM, ST																																								
Stage 2: Recruitment, intervention and data collection																																									
Sample recruitment	CI																																								
Immediate follow-up	CI, CB																																								
Neurodevelopment follow-up	CB																																								
Data collection	HC, DM																																								
Stage 3: Data analysis and interpretation of results																																									
Statistical analysis	ST																																								
Interpretation	PI																																								
Conclusions	PI																																								
Stage 4: Edition and publication																																									
Paper redaction	PI																																								
Publication and dissemination	PI																																								

Table 6. Study chronogram. *Staff abbreviations or acronyms are detailed in Section 9.1 (Research team members). The months of each year are represented in chronological order using their initial letters.*

10. BUDGET

Personnel: data managers, the principal investigators, coordinators, co-investigators and collaborators will belong to the paediatric or neonatology team from each hospital. This integration ensures that the research is a part of their clinical practice, and no additional hours are expected from them, thus no additional costs will be incurred for their activities.

Regarding paediatric neurologists, they will experience an increased workload. To ensure their involvement and compensate for the extra work, an estimated rate of 13.50€ per hour has been calculated. Given that they can manage two patients per hour, the total additional time expected is 316 hours. Each neurologist will receive compensation based on the number of patients referred to them for follow-up.

As for the statistical analysis, a professional statistician must be hired. Their workload is estimated to be approximately 30 hours per month, with a total of 3 months to complete the data analysis, resulting in 90 hours of work. The estimated cost if 40€ per hour, based on the average price of their work.

Material: documents will be printed to provide to all patients included in the clinical trial, including all annexes from this document. We estimate that consent form and consent information document will at least be printed twice the amount necessary as they will be delivered to every pregnant patient admitted for delivery and not all of them will be finally taking part in the clinical trial.

In terms of material necessary to perform intact cord management, the LifeStart™ Bed has an estimated price of 6000€ (73). Each participating hospital will need to install at least one LifeStart™ Bed. Assuming all seven hospitals agree to participate, a total of seven beds will be required, amounting to €42000.

The rest of the material necessary to develop neonatal resuscitation and Neonatal Intensive Care Unit (NICU) care for the infants involved will be provided by each hospital, and no extra expenses will be necessary.

Travel expenses: for the proper development of this clinical trial, meetings and training sessions will be necessary. For the initial meeting, the general coordinator, principal investigators and hospital coordinators will meet at Trueta Hospital of Girona, necessitating 6 trips, one for each hospital coordinator, with an estimated cost of 20€ per participant. The follow-up meetings, taking place every 3 moths, will be conducted online, so no further expenses will be derived from them.

As for the training sessions, they will be developed by the general coordinator, who will travel to each participating hospital for a total of 5 days, estimating a 20€ cost per day. This cost will not be applicable for the Trueta Hospital of Girona, as there will not be extra hours involved, and no trips will be necessary.

The patient neurodevelopment follow-up visits will take place in each participating hospital. To cover travel expenses for parents, we will estimate 10€ per visit, with a total of 4 visits for each patient.

Publication and dissemination: for the elaboration and publication of our article once we obtain the results of this clinical trial, around 3500 words will be necessary to deliver the conclusions. The article must be written in English using proper vocabulary. For the correction, an estimated price of 5,92€ every 100 words has been calculated (74). The corrected article will then be published, and the estimated publication fees for high impact international editorial journals amount to a total of 3000€ (75).

Finally, for the dissemination of this research, the two main investigators will attend the National Neonatology Congress, taking place in 2030. The estimate cost of this congress is 500€ per attendant (76) and travel expenses will also be covered, estimating at least 100€ per attendant for the trips and hotel accommodation. This budget may be modified if congress fees variate, or if the location increases or decreases expenses on the trip.

Insurance: provided that our intervention has proven to be safe in other clinical trials and it is considered of low risk for both the pregnant patient and the newborn, a liability insurance will not be necessary to develop this clinical trial.

Table 7. Budget summary.

EXPENSES	UNIT COST	UNIT	TOTAL
	PERSONNEL		
Professional statistician	40 €/h	90	3600 €
Paediatric neurologists	13.5 €/h	316	4266 €
			Subtotal: *7866 €*
	MATERIAL		
Informed consent printing	0,10 €	316	31,60 €
Patient information document printing	0,40 €	316	126,40 €
ASQ-3 Questionnaires	3 €	158	474 €
Data collection sheet printing	0,50 €	158	79 €
Consent withdrawal printing	0,10 €	158	15,80 €
LifeStart™ Bed	6000 €	7	42000 €
			Subtotal: 42726,80 *€*
	TRAVEL EXPENSES		
Initial meeting	20 €	6	120 €
Training sessions	20 €	30	600 €
Patient follow-up	10 €	632	6320 €
			Subtotal: *7040 €*
	PUBLICATION AND DISSEMINATION		
English correction	5,92 € / 100 words	35	207,20 €
Publication fees	3000 €	1	3000 €
SENeo congress	500 €	2	1000 €
Travel expenses	100 €	2	200 €
			Subtotal: *4407,20 €*
Total: 62040 €			

11. FEASIBILITY

The feasibility of our clinical trial is supported by several factors. Firstly, conducting it in different hospitals from our region, all belonging to the "Servei Català de la Salut" and equipped with Neonatal Intensive Care Units (NICUs) and neonatology specialized teams, ensures that the necessary infrastructure and trained personnel are available, which is crucial for the successful development of each phase of the study. Moreover, hospitals will be provided with the necessary material to develop our intervention using a standardized protocol, making them comparable.

Our intervention has proven to be safe, not involving any additional insurances to perform this trial. Furthermore, developing new evidence will allow us to develop an agreed-upon protocol in our region, changing the paradigm of neonatal resuscitation and providing better outcomes for these fragile patients.

Additionally, the estimated cost of this trial is considered low and affordable, and funding for clinical research will be sought from various health associations, ensuring the viability of conducting this study.

Finally, our sample size is 158, deemed feasible to acquire during one year as this study is multicentre. Even including the follow-up period, which will take up to four years per patient, the totality of our research project will be concluded by the end of year 2030, taking less than six years total. The total length of the investigation is considered appropriate and viable.

Overall, out design and planning indicate that this trial is feasible and well-structured to generate valuable evidence in neonatal resuscitation.

12. CLINICAL AND HEALTHCARE IMPACT

Current guidelines from different societies only recommend delaying cord clamping when considered feasible and secure for both the infant and the mother within the framework of the “golden minute” during the first steps of cardiopulmonary resuscitation in non-vigorous newborns.

New evidence over the past years has proven that intact cord management is a safe intervention when applying resuscitation, but every study available recommends expanding the research in this field, and many of the latest clinical trials have excluded non-vigorous infants from their population.

Management of the umbilical cord has changed widely in newborns not needing cardiopulmonary resuscitation. Receiving an adequate blood volume from placental transfusion plays a major role in neonatal transition. In distressed or non-vigorous newborns, this role is even greater as they are in need for further assistance than those born correctly.

With our clinical trial we aim to amplify the knowledge on this subject, explore the benefits of intact cord management in non-vigorous infants, and demonstrate that this practice should be implemented widely.

Once we reach the initial results from this study, a local protocol will be elaborated to implement intact cord management during neonatal resuscitation in the delivery room in our region. This will expand access to this beneficial practice to a broad fragile population and improve standards of care in this field.

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14. ANNEXES

ANNEX 1: PATIENT INFORMATION DOCUMENT

DOCUMENTO DE INFORMACIÓN PARA EL/LA PACIENTE

Nombre del estudio: Protocolo para la implementación de la resucitación neonatal con cordón íntegro en sala de partos.

Centro asistencial:

Bienvenido/a,

Nos dirigimos a usted para informarle de que actualmente se está realizando un estudio de investigación para el cual nos gustaría solicitar su participación. Este estudio se lleva a cabo en el Servicio de Neonatología de diferentes hospitales de la región, y usted se encuentra actualmente en atención en uno de ellos.

El estudio ha sido aprobado por el Comité de Ética de Investigación Clínica, de acuerdo con la legislación vigente y respetando los principios éticos enunciados en la Declaración de Helsinki. Los profesionales que participan en él cumplen con las guías de buena práctica clínica.

Este documento detalla el motivo de realización de este estudio y en qué consistirá su participación, con el fin de que pueda decidir libremente si desea formar parte. Le rogamos lea con atención y no dude en manifestar cualquier consulta que tenga al equipo de investigación en todo momento.

Participación y retirada voluntarias

Usted, como progenitor/tutor legal, puede decidir voluntaria y libremente si desea que su hijo/a forme parte de este estudio. Si decide participar, sigue teniendo la posibilidad de revocar su consentimiento en todo momento, sin dar ninguna explicación ni tener ninguna repercusión negativa para usted y su hijo/a.

No obstante, debe saber que los datos que se hayan obtenido hasta el momento de la retirada en caso de que esta se produzca, podrán ser utilizados para los fines detallados en este documento y se podrán conservar en cumplimiento con la legislación actual correspondiente.

Objetivo y finalidad del estudio

Este estudio tiene la finalidad de determinar si la resucitación cardiopulmonar neonatal con cordón íntegro genera mejores resultados que la estrategia actual (resucitación cardiopulmonar con clampaje precoz del cordón umbilical), con la finalidad de realizar un protocolo estandarizado basado en los resultados de nuestro estudio para aplicar esta nueva estrategia en nuestra región.

Existen amplios beneficios demostrados del clampaje tardío del cordón umbilical, pero pocos estudios evalúan su aplicabilidad en estas situaciones de emergencia. Conociendo que los perjuicios para el neonato serán mínimos o inexistentes, tenemos el objetivo de demostrar que genera beneficios muy amplios en neonatos más frágiles que requieren reanimación, para poder después aplicarlo y mejorar los resultados de la reanimación.

Metodología e intervención:

En este estudio es necesario obtener un total de 158 pacientes, que será distribuidos de manera aleatoria en dos grupos:

- Grupo intervención: realizaremos la resucitación cardiopulmonar neonatal con cordón íntegro.
- Grupo control: realizaremos la estrategia actual de resucitación cardiopulmonar con clampaje precoz.

Todos los pacientes ingresarán en la unidad de cuidados intensivos neonatal tras el nacimiento para un seguimiento clínico y analítico, donde se explorarán diferentes parámetros para evaluar las diferencias entre ambos grupos. Una vez hayan obtenido el alta hospitalaria, se realizará un seguimiento en consultas externas de neurología pediátrica a los seis (6), doce (12), veinticuatro (24) y cuarenta y dos (42) meses de vida para evaluar su desarrollo neurológico.

Es importante destacar que aquellos neonatos para los que se haya obtenido el consentimiento, pero que finalmente no necesiten reanimación, serán excluidos de este estudio al no cumplir con este requisito.

Potenciales riesgos y beneficios del estudio

Como beneficios principales de este estudio esperamos obtener una mejoría clínica del neonato de forma inmediata tras la resucitación. Asimismo, la disminución de complicaciones neonatales como son infecciones, alteraciones hematológicas, secuelas neurológicas o patología respiratoria, entre otras.

No se anticipan riesgos significativos, ya que la intervención ha demostrado ser segura, eficaz y beneficiosa en muchos de los aspectos mencionados. Además, en aquellos neonatos sin necesidad de reanimación, nuestra intervención es la técnica de elección en la actualidad para el manejo del cordón umbilical.

Alternativas al procedimiento

Si no desea participar en el estudio, se realizará el manejo actual de reanimación neonatal, cortando el cordón umbilical antes de iniciar las maniobras. En caso de que nuevas contraindicaciones de la intervención surjan durante el estudio, se realizará la retirada inmediata de todos los pacientes y pasarán al protocolo actual.

Protección de datos y confidencialidad

Tanto el centro hospitalario como el equipo investigador son responsables del tratamiento de sus datos y se comprometen a cumplir con la Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales y el Reglamento (UE) 2016/679 del Parlamento europeo y del Consejo de 27 abril de 2016 de Protección de Datos (RGPD).

Los datos recopilados se tratarán de manera estrictamente confidencial, siendo identificados mediante un código, y solo el equipo investigador podrá relacionar estos datos con su hijo/a. Toda información personal únicamente se conservará por el centro para cuidados de salud y por el equipo investigador para otros fines de investigación científica si hubiera otorgado su consentimiento para hacerlo y si así lo permite la ley y los requisitos éticos aplicables.

Una vez finalizado el estudio, los resultados y conclusiones obtenidas se divulgarán en revistas científicas y congresos médicos, con el fin de que otros centros y

pacientes puedan beneficiarse de ellos. En este proceso divulgativo, se garantiza el tratamiento anónimo de los datos de carácter personal, respetando la confidencialidad de dichos datos.

Le informamos que tiene derecho a acceder, rectificar o cancelar los datos que ha facilitado para este estudio, y puede limitar el tratamiento de aquellos que sean incorrectos, solicitar una copia, o que se trasladen a un tercero.

Para ejercitar sus derechos, o en caso de que el participante desee ampliar información sobre el tratamiento de sus datos personales, se podrá dirigir al un miembro del equipo investigador del estudio, cuyos datos se especifican al final de este documento. Asimismo, tiene derecho a dirigirse a la Agencia de Protección de Datos si no quedase satisfecho.

Información sobre resultados

En caso de que lo solicite, al final del estudio y de acuerdo con el artículo 27 de la Ley 14/2007 de Investigación Biomédica, se le podrá facilitar información sobre los resultados de este trabajo de investigación.

Responsabilidad y seguro

No se esperan problemas derivados de este ensayo clínico. En caso de sufrir algún problema contacte con su equipo investigador inmediatamente.

Este ensayo no cuenta con póliza de seguro ya que todas las técnicas han sido previamente aprobadas y son seguras, por lo que no se optará a compensación económica en ningún caso.

Datos de contacto del equipo investigador

Nombre: .....

Teléfono: .....

Correo: .....

Gracias por su atención.

ANNEX 2: INFORMED CONSENT DOCUMENT

CONSENTIMIENTO INFORMADO

Nombre del estudio: Protocolo para la implementación de la resucitación neonatal con cordón íntegro en sala de partos.

Centro asistencial:

Declaración del progenitor o tutor legal:

Yo, _____ , con DNI _____ , como madre/padre/tutor legal de _____ (nombre y apellidos del paciente), declaro haber revisado el material informativo acerca del estudio, haber tenido la oportunidad de plantear todas las preguntas pertinentes y resolver mis inquietudes respecto al estudio, y haber recibido la suficiente información por parte de un miembro del equipo de investigación.

Comprendo que la participación de _____ (nombre y apellidos del paciente), es totalmente voluntaria y no remunerada, y que tengo la opción de cambiar de opinión en cualquier momento, retirando mi consentimiento sin que eso tenga ninguna repercusión negativa.

Concedo autorización para que el equipo de investigación utilice los datos del historial clínico de _____ (nombre y apellidos del paciente) con fines relacionados con el estudio, garantizando la confidencialidad de dicha información.

Certifico haber recibido una copia del Documento de Información para la Paciente y una copia de este Consentimiento Informado.

☐ Si ☐ No

Nombre y firma del investigador:

_____

Fecha: ___ /___ /___

Firma de la progenitor/tutor legal:

_____

Fecha: ___ /___ /___

ANNEX 3: CONSENT WITHDRAWAL DOCUMENT

REVOCACIÓN DEL CONSENTIMIENTO INFORMADO

Nombre del estudio: Protocolo para la implementación de la resucitación neonatal con cordón íntegro en sala de partos.

Centro asistencial:

Yo, _____ , con DNI _____ , como padre/madre/tutor legal de _____ (nombre y apellidos del paciente), en mi propio nombre y derecho manifiesto mi voluntad de revocar el consentimiento prestado, en fecha de _____ para la participación de mi hijo/hija en el estudio previamente mencionado.

Nombre y firma del investigador:

_____

Fecha: ___ /___ /___

Firma de la progenitor/tutor legal:

_____

Fecha: ___ /___ /___

ANNEX 4: ASQ-3 (6 MONTHS)

ASQ-3™ Ages & Stages Questionnaires®

5 meses 0 días a 6 meses 30 días

Cuestionario de 6 meses

Favor de proveer los siguientes datos. Al completar este formulario, use solamente una pluma de tinta negra o azul y escriba legiblemente con letra de molde.

Fecha en que se completó el cuestionario: D D M M A A A A

Información del bebé

Nombre del bebé: | Inicial de su segundo nombre: | Apellido(s) del bebé:

Fecha de nacimiento del bebé: D D M M A A A A

Para bebés prematuros, si el parto ocurrió 3 semanas o más antes de la fecha proyectada, # de semanas que se adelantó:

Sexo del bebé: ◯ Masculino ◯ Femenino

Información de la persona que está llenando este cuestionario

Nombre: | Inicial de su segundo nombre: | Apellido(s):

Dirección:

Parentesco con el bebé: ◯ Padre/madre ◯ Tutor ◯ Maestro/a ◯ Educador/a o asistente de preescolar ◯ Abuelo/a u otro pariente ◯ Madre/padre de acogida ◯ Otro/a:

Ciudad: | Estado/Provincia: | Código postal:

País: | # de teléfono de casa: | Otro # de teléfono:

Su dirección electrónica:

Los nombres de las personas que le están ayudando a llenar este cuestionario:

INFORMACION DEL PROGRAMA

de identificación del bebé:

Edad al realizar la evaluación ASQ, en meses y días: M M D D

de identificación del programa:

Si es bebé prematuro/a, edad ajustada, en meses y días: M M D D

Nombre del programa:

E102060100

ASQ-3™

Cuestionario de 6 meses

5 meses 0 días a 6 meses 30 días

En las siguientes páginas Ud. encontrará una serie de preguntas sobre diferentes actividades que generalmente hacen los bebés. Puede ser que su bebé ya pueda hacer algunas de estas actividades, y que todavía no haya realizado otras. Después de leer cada pregunta, por favor marque la respuesta que indique si su bebé hace la actividad regularmente, a veces, o todavía no.

Puntos que hay que recordar:

- ☑ Asegúrese de intentar cada actividad con su bebé antes de contestar las preguntas.
- ☑ Complete el cuestionario haciendo las actividades con su bebé como si fueran un juego divertido.
- ☑ Asegúrese de que su bebé haya descansado y comido.
- ☑ Por favor, devuelva este cuestionario antes de esta fecha: _____.

Notas:

_____

_____

_____

_____

_____

COMUNICACION

	SI	A VECES	TODAVIA NO	
1. ¿Hace chillidos agudos su bebé?	◯	◯	◯	___
2. Al experimentar con sonidos, ¿su bebé hace sonidos de tono bajo, como gruñir o rugir?	◯	◯	◯	___
3. Si Ud. llama a su bebé cuando ella no lo/la puede ver, ¿voltea la cabeza en la dirección de su voz?	◯	◯	◯	___
4. Cuando escucha un ruido fuerte, ¿su bebé voltea a ver de dónde viene?	◯	◯	◯	___
5. ¿Hace su bebé sonidos como "da", "ga", "ka", y "ba"?	◯	◯	◯	___
6. Si Ud. imita los sonidos que hace su bebé, ¿ella los repite?	◯	◯	◯	___

TOTAL EN COMUNICACION ___

MOTORA GRUESA

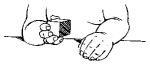
	SI	A VECES	TODAVIA NO	
1. Al estar acostado boca arriba, ¿levanta su bebé las piernas lo suficiente para poder verse los pies?	◯	◯	◯	___
2. ¿Cuando está boca abajo, estira los dos brazos y levanta todo el pecho de la cama o del suelo?	◯	◯	◯	___
3. Cuando está acostada boca arriba, ¿su bebé puede darse la vuelta para estar boca abajo, sacando los brazos hacia los lados del cuerpo?	◯	◯	◯	___
4. Cuando Ud. sienta a su bebé en el suelo, ¿él usa las manos para apoyarse? *(Si su bebé ya puede sentarse sin apoyarse con las manos, marque "sí" en esta pregunta.)* 	◯	◯	◯	___

MOTORA GRUESA *(continuación)*

		SI	A VECES	TODAVIA NO	
5.	Si Ud. agarra las manos de su bebé para ayudarle a mantener el equilibrio, ¿ella puede sostener su propio peso mientras está de pie? 	◯	◯	◯	___
6.	¿Puede su bebé ponerse en la postura para gatear apoyándose en las manos y en las rodillas? 	◯	◯	◯	___

TOTAL EN MOTORA GRUESA ___

MOTORA FINA

		SI	A VECES	TODAVIA NO	
1.	¿Toma su bebé un juguete que se le ofrece, lo mira, lo agita, o lo muerde por aproximadamente un minuto?	◯	◯	◯	___
2.	¿Su bebé extiende las dos manos a la vez para agarrar un juguete?	◯	◯	◯	___
3.	¿Extiende la mano para tomar una migaja de pan o un Cheerio (cereal de desayuno) y/o lo toca con el dedo o la mano? *(Si su bebé ya puede agarrar un objeto pequeño, marque "sí" en esta pregunta.)* 	◯	◯	◯	___
4.	¿Puede agarrar un juguete pequeño y tenerlo en la palma de la mano, sujetándolo con los dedos? 	◯	◯	◯	___
5.	¿*Intenta* agarrar una migaja de pan o un Cheerio (cereal de desayuno) usando el dedo pulgar y todos los demás dedos, haciendo un movimiento como de rastrillo, incluso si no puede agarrarlo? *(Si ya puede agarrar una migaja o un Cheerio de esta manera, marque "sí" en esta pregunta.)* 	◯	◯	◯	___
6.	¿Agarra un juguete pequeño con una sola mano? 	◯	◯	◯	___

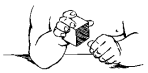
TOTAL EN MOTORA FINA ___

RESOLUCION DE PROBLEMAS

		SI	A VECES	TODAVIA NO	
1.	Cuando hay un juguete enfrente de su bebé, ¿intenta alcanzarlo usando las dos manos?	◯	◯	◯	___
2.	Cuando está boca arriba, ¿vuelve la cabeza para buscar un juguete cuando lo deja caer? *(Si al dejarlo caer ya puede recogerlo, marque "sí" en esta pregunta.)*	◯	◯	◯	___
3.	Al estar boca arriba, ¿su bebé intenta agarrar un juguete que se le cayó si lo puede ver?	◯	◯	◯	___

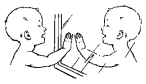
E102060300

RESOLUCION DE PROBLEMAS *(continuación)*

		SI	A VECES	TODAVIA NO	
4.	¿Su bebé agarra un juguete y se lo mete en la boca? 	○	○	○	___
5.	¿Se pasa un juguete de una mano a la otra? 	○	○	○	___
6.	¿Juega golpeando un juguete contra el suelo o contra la mesa? 	○	○	○	___

TOTAL EN RESOLUCION DE PROBLEMAS ___

SOCIO-INDIVIDUAL

		SI	A VECES	TODAVIA NO	
1.	Cuando está delante de un espejo grande, ¿empieza su bebé a sonreír o a hacer sonidos? 	○	○	○	___
2.	¿Se comporta de una manera distinta con personas desconocidas que con Ud. o con otras personas que conoce? *(Reacciones a desconocidos pueden incluir mirarlos fijamente, fruncir el ceño, retraerse, o llorar.)*	○	○	○	___
3.	Al estar boca arriba, ¿intenta jugar agarrándose el pie? 	○	○	○	___
4.	Al estar delante de un espejo grande, ¿intenta tocar el espejo con las manos? 	○	○	○	___
5.	Al estar boca arriba, ¿su bebé intenta meterse el pie en la boca? 	○	○	○	___
6.	¿Intenta agarrar un juguete que no puede alcanzar? *(Puede que intente darse la vuelta, girar el tronco estando boca abajo, o gatear para agarrarlo.)*	○	○	○	___

TOTAL EN SOCIO-INDIVIDUAL ___

E102060400

OBSERVACIONES GENERALES

Los padres y proveedores pueden utilizar el espacio después de cada pregunta para hacer comentarios adicionales.

1. ¿Usa su bebé ambas manos y ambas piernas igualmente bien? Si contesta "no", explique: ◯ SI ◯ NO

2. Al ponerlo/la de pie, ¿su bebé pone los pies completamente planos sobre el suelo la mayoría de la veces? Si contesta "no", explique: ◯ SI ◯ NO

3. ¿Le preocupa que su bebé sea muy callado/a o que no haga sonidos como otros bebés? Si contesta "sí", explique: ◯ SI ◯ NO

4. ¿Tiene algún familiar con historia de sordera o cualquier otro impedimento auditivo? Si contesta "sí", explique: ◯ SI ◯ NO

5. ¿Tiene Ud. alguna preocupación sobre la visión de su bebé? Si contesta "sí", explique: ◯ SI ◯ NO

E102060500

OBSERVACIONES GENERALES *(continuación)*

6. ¿Ha tenido su bebé algún problema de salud en los últimos meses? Si contesta "sí", explique: ◯ SI ◯ NO

7. ¿Tiene alguna preocupación sobre el comportamiento de su bebé? Si contesta "sí", explique: ◯ SI ◯ NO

8. ¿Le preocupa algún aspecto del desarrollo de su bebé? Si contesta "sí", explique: ◯ SI ◯ NO

E102060600

ASQ-3: Compilación de datos **6** meses

5 meses 0 días a 6 meses 30 días

Nombre del bebé: _____ Fecha de hoy: _____

de identificación del bebé: _____ Fecha de nacimiento: _____

Nombre del programa/proveedor: _____ Para bebés prematuros, ¿seleccionó el cuestionario apropiado tomando en cuenta la edad ajustada del bebé? ◯ Sí ◯ No

1. CALIFIQUE EL CUESTIONARIO Y PASE EL PUNTAJE TOTAL DE CADA SECCION AL GRAFICO DE ABAJO: Véase *ASQ-3 User's Guide* para obtener más detalles, incluyendo la manera de ajustar el puntaje si faltan respuestas a algunas preguntas. Califique cada pregunta (SI = 10, A VECES = 5, TODAVIA NO = 0). Sume los puntos de cada pregunta, anotando el puntaje total en la línea provista al final de cada sección del cuestionario. En el gráfico de abajo, anote el puntaje total de cada sección, y rellene el círculo correspondiente.

Área	Límite	Puntaje Total	0	5	10	15	20	25	30	35	40	45	50	55	60
Comunicación	29.65		●	●	●	●	●	●	○	○	○	○	○	○	○
Motora gruesa	22.25		●	●	●	●	●	○	○	○	○	○	○	○	○
Motora fina	25.14		●	●	●	●	●	●	○	○	○	○	○	○	○
Resolución de problemas	27.72		●	●	●	●	●	●	○	○	○	○	○	○	○
Socio-individual	25.34		●	●	●	●	●	●	○	○	○	○	○	○	○

2. TRANSFIERA LAS RESPUESTAS DE LA SECCION TITULADA "OBSERVACIONES GENERALES": Las respuestas escritas en negrita o con mayúsculas requerirán un seguimiento. Véase el capítulo 6 del *ASQ-3 User's Guide* para obtener información sobre las pautas a seguir.

1. ¿Usa ambas manos y ambas piernas por igual? Sí **NO**
   Comentarios:
2. ¿Normalmente pone los pies completamente planos en el suelo? Sí **NO**
   Comentarios:
3. ¿Preocupaciones porque no hace sonidos? **SI** No
   Comentarios:
4. Historial: ¿Hay problemas auditivos en la familia? **SI** No
   Comentarios:
5. ¿Preocupaciones sobre la vista? **SI** No
   Comentarios:
6. ¿Hay problemas de salud recientes? **SI** No
   Comentarios:
7. ¿Preocupaciones sobre comportamiento? **SI** No
   Comentarios:
8. ¿Otras preocupaciones? **SI** No
   Comentarios:

3. INTERPRETACION DEL PUNTAJE Y RECOMENDACIONES PARA EL SEGUIMIENTO DEL ASQ: Para determinar el nivel de seguimiento apropiado, hay que tomar en cuenta el *Puntaje total* de cada sección, las respuestas de la sección titulada "Observaciones generales", y también factores adicionales, tales como considerar si el bebé tiene oportunidades para practicar las habilidades.

Si el *Puntaje total* está dentro del área ▭, el puntaje del bebé está por encima de las expectativas, y el desarrollo del bebé parece estar bien hasta ahora.

Si el *Puntaje total* está dentro del área ▭, el puntaje está apenas por encima de las expectativas. Proporcione actividades adicionales para ayudarle al bebé y vigile su progreso.

Si el *Puntaje total* está dentro del área ■, el puntaje está debajo de las expectativas. Quizás se requiera una evaluación adicional más a fondo.

4. SEGUIMIENTO DEL ASQ: Marque todos los que apliquen.

_____ Dar actividades adicionales y reevaluar en _____ meses.

_____ Compartir los resultados con su médico familiar (primary health care provider).

_____ Referirlo/la para una evaluación auditiva, visual, o de comportamiento. (Marque con un círculo todos los que apliquen.)

_____ Referirlo/la a un médico familiar u otra agencia comunitaria (favor de escribir la razón): _____.

_____ Referirlo/la a un programa de intervención temprana/educación especial para niños preescolares para hacer una evaluación adicional.

_____ No tomar medidas adicionales en este momento.

_____ Medida adicional (favor de escribirla): _____ .

5. OPCIONAL: Anote las respuestas específicas (S = SI, V = A VECES, N = TODAVIA NO, R = falta esta respuesta).

	1	2	3	4	5	6
Comunicación						
Motora gruesa						
Motora fina						
Resolución de problemas						
Socio-individual						

P102060700

ANNEX 5: ASQ-3 (12 MONTHS)

ASQ-3™ Ages & Stages Questionnaires®

11 meses 0 días a 12 meses 30 días

Cuestionario de 12 meses

Favor de proveer los siguientes datos. Al completar este formulario, use solamente una pluma de tinta negra o azul y escriba legiblemente con letra de molde.

Fecha en que se completó el cuestionario: D D M M A A A A

Información del bebé

Nombre del bebé:

Inicial de su segundo nombre:

Apellido(s) del bebé:

Fecha de nacimiento del bebé: D D M M A A A A

Para bebés prematuros, si el parto ocurrió 3 semanas o más antes de la fecha proyectada, # de semanas que se adelantó:

Sexo del bebé: ◯ Masculino ◯ Femenino

Información de la persona que está llenando este cuestionario

Nombre:

Inicial de su segundo nombre:

Apellido(s):

Dirección:

Parentesco con el bebé: ◯ Padre/madre ◯ Tutor ◯ Maestro/a ◯ Educador/a o asistente de preescolar ◯ Abuelo/a u otro pariente ◯ Madre/padre de acogida ◯ Otro/a:

Ciudad:

Estado/Provincia:

Código postal:

País:

de teléfono de casa:

Otro # de teléfono:

Su dirección electrónica:

Los nombres de las personas que le están ayudando a llenar este cuestionario:

INFORMACION DEL PROGRAMA

de identificación del bebé:

Edad al realizar la evaluación ASQ, en meses y días: M M D D

de identificación del programa:

Si es bebé prematuro/a, edad ajustada, en meses y días: M M D D

Nombre del programa:

E102120100

ASQ-3™

Cuestionario de 12 meses

11 meses 0 días a 12 meses 30 días

En las siguientes páginas Ud. encontrará una serie de preguntas sobre diferentes actividades que generalmente hacen los bebés. Puede ser que su bebé ya pueda hacer algunas de estas actividades, y que todavía no haya realizado otras. Después de leer cada pregunta, por favor marque la respuesta que indique si su bebé hace la actividad regularmente, a veces, o todavía no.

Puntos que hay que recordar:

- ☑ Asegúrese de intentar cada actividad con su bebé antes de contestar las preguntas.
- ☑ Complete el cuestionario haciendo las actividades con su bebé como si fueran un juego divertido.
- ☑ Asegúrese de que su bebé haya descansado y comido.
- ☑ Por favor, devuelva este cuestionario antes de esta fecha: _____.

Notas:

_____

_____

_____

_____

_____

COMUNICACION

	SI	A VECES	TODAVIA NO	
1. ¿Puede hacer dos sonidos similares como "ba-ba", "da-da", o "ga-ga"? *(No es necesario que los sonidos tengan significado.)*	◯	◯	◯	___
2. Cuando Ud. se lo pide, ¿puede su bebé jugar a algún juego infantil sin que Ud. se lo demuestre primero (por ejemplo, decir adiós, esconderse tapándose los ojos, aplaudir, o indicar que tan grande es algo)?	◯	◯	◯	___
3. ¿Sigue su bebé instrucciones sencillas, como por ejemplo, "ven acá", dámelo", o devuélvelo" ***sin*** que Ud. le haga gestos para que entienda lo que le está pidiendo?	◯	◯	◯	___
4. ¿Dice su bebé tres palabras como "mamá", "dada", y "baba"? *(Una "palabra" se define como un sonido o un grupo de sonidos que siempre repite su bebé al referirse a alguien o a alguna cosa concreta.)*	◯	◯	◯	___
5. Al preguntarle, ¿dónde está la pelota (el gorro, el zapato, etc.)?, ¿su bebé mira el objeto? *(Asegúrese de que el objeto esté presente. Marque "sí" en esta pregunta si reconoce por lo menos un objeto.)*	◯	◯	◯	___
6. Cuando su bebé quiere algo, ¿lo ***señala con el dedo*** para comunicárselo a Ud.?	◯	◯	◯	___
			TOTAL EN COMUNICACION	___

MOTORA GRUESA

	SI	A VECES	TODAVIA NO	
1. Al estar agarrado a un mueble, ¿puede su bebé agacharse para recoger un juguete del suelo y después volver a ponerse de pie? 	◯	◯	◯	___
2. Al estar agarrada a un mueble, ¿puede su bebé agacharse, manteniendo el control (sin caerse al suelo)?	◯	◯	◯	___

MOTORA GRUESA *(continuación)*

	SI	A VECES	TODAVIA NO	
3. ¿Camina por la casa su bebé, agarrándose a los muebles con una sola mano?	○	○	○	___
4. Si Ud. le agarra ambas manos para ayudarle a mantener el equilibrio, ¿su bebé da unos pasitos hacia adelante sin tropezar o caerse? *(Si su bebé ya puede caminar solo, marque "si" en esta pregunta.)* 	○	○	○	___
5. Cuando Ud. le toma *una* mano para que no se caiga, ¿puede su bebé dar unos pasitos hacia adelante? *(Si su bebé ya camina sola, marque "sí" en esta pregunta.)* 	○	○	○	___
6. ¿Su bebé puede ponerse de pie y dar algunos pasitos hacia adelante sin ninguna ayuda o soporte?	○	○	○	___

TOTAL EN MOTORA GRUESA ___

MOTORA FINA

	SI	A VECES	TODAVIA NO	
1. Después de intentarlo una o dos veces, ¿puede agarrar su bebé un segmento de cuerda con los dedos índice y pulgar? *(La cuerda puede estar atada a un juguete.)* 	○	○	○	___
2. ¿Puede agarrar una migaja de pan o un Cheerio (cereal de desayuno) con *las yemas* de los dedos (índice y pulgar)? Puede apoyar el brazo o la mano en la mesa mientras que lo hace. 	○	○	○	___
3. ¿Puede poner un juguete pequeño en la mesa (en el sofá o en el suelo), sin dejarlo caer, y después levantar la mano de encima del juguete?	○	○	○	___
4. Sin apoyar la mano o el brazo en la mesa, ¿puede agarrar una migaja de pan o un Cheerio (cereal de desayuno) con *las yemas* de los dedos (índice y pulgar)?* 	○	○	○	___ *
5. ¿Puede lanzar su bebé una pelota pequeña, moviendo el brazo hacia adelante por encima del hombro? *(Si simplemente la deja caer, marque "todavía no" en esta pregunta.)* 	○	○	○	___

MOTORA FINA *(continuación)*

	SI	A VECES	TODAVIA NO	
6. ¿Su bebé le ayuda a Ud. a darle la vuelta a las hojas de un libro? *(Ud. puede darle la página para que ella la agarre.)*	◯	◯	◯	____

TOTAL EN MOTORA FINA ____

**Si marcó "sí" o "a veces" en la pregunta 4, marque "sí" en la pregunta 2.*

RESOLUCION DE PROBLEMAS

	SI	A VECES	TODAVIA NO	
1. Al tener un juguete pequeño en cada mano, ¿su bebé intenta golpearlos uno con otro (como cuando se aplaude)?	◯	◯	◯	____
2. ¿Su bebé agarra o usa el dedo índice para tocar un Cheerio (cereal de desayuno) o una migaja de pan que está dentro de una botella transparente (por ejemplo una botella de refresco o un biberón)?	◯	◯	◯	____
3. Después de verle a Ud. esconder un juguete pequeño debajo de una hoja de papel o de un trozo de tela, ¿puede su bebé encontrarlo? *(Asegúrese de que el juguete esté completamente escondido.)*	◯	◯	◯	____
4. Si Ud. pone un juguete en un tazón o en una caja, ¿su bebé lo/la imita queriendo meter un juguete también, aunque pueda ser que no lo suelte? *(Si ya suelta el juguete en el tazón o en la caja, marque "sí" en esta pregunta.)*	◯	◯	◯	____
5. ¿Su bebé pone dos juguetes, uno tras otro, en un recipiente como una caja o un tazón grande? *(Puede enseñarle cómo se hace.)** 	◯	◯	◯	____ *
6. Si Ud. traza rayones o garabatos en un papel con una crayola (o con un lápiz o una pluma), ¿hace su bebé lo mismo, imitándole a Ud.? *(Si ya sabe trazar solo, marque "sí" en esta pregunta.)*	◯	◯	◯	____

TOTAL EN RESOLUCION DE PROBLEMAS ____

**Si marcó "sí" o "a veces" en la pregunta 5, marque "sí" en la pregunta 4.*

SOCIO-INDIVIDUAL

	SI	A VECES	TODAVIA NO	
1. Al extenderle la mano y pedirle su juguete, ¿su bebé se lo ofrece aunque no lo suelte? *(Si ya suelta el juguete para dárselo, marque "sí" en esta pregunta.)*	◯	◯	◯	____
2. Cuando Ud. viste a su bebé, ¿puede él meter el brazo por la manga de la camisa una vez que Ud. le haya metido la mano en la bocamanga?	◯	◯	◯	____
3. Cuando Ud. le extiende la mano para pedirle un juguete, ¿su bebé lo suelta para que Ud. lo tome?	◯	◯	◯	____
4. Al vestir a su bebé, ¿levanta ella el pie cuando Ud. le va a poner el zapato, el calcetín, o el pantalón?	◯	◯	◯	____

E102120400

SOCIO-INDIVIDUAL *(continuación)*

	SI	A VECES	TODAVIA NO	
5. Al jugar a la pelota con su bebé, ¿su bebé la tira o la hace rodar para que Ud. se la devuelva?	◯	◯	◯	___
6. ¿Juega su bebé con una muñeca o con un muñeco de peluche, abrazándolo?	◯	◯	◯	___

TOTAL EN SOCIO-INDIVIDUAL ___

OBSERVACIONES GENERALES

Los padres y proveedores pueden utilizar el espacio después de cada pregunta para hacer comentarios adicionales.

1. ¿Usa su bebé ambas manos y ambas piernas igualmente bien? Si contesta "no", explique: ◯ SI ◯ NO

2. ¿Experimenta su bebé con sonidos, o parece formar nuevas palabras? Si contesta "no", explique: ◯ SI ◯ NO

3. Cuando está de pie, ¿pone su bebé los pies completamente planos sobre el suelo la mayoría de las veces? Si contesta "no", explique: ◯ SI ◯ NO

4. ¿Le preocupa que su bebé sea muy callado/a o que no haga sonidos como otros bebés? Si contesta "sí", explique: ◯ SI ◯ NO

E102120500

OBSERVACIONES GENERALES *(continuación)*

5. ¿Tiene algún familiar con historia de sordera o cualquier otro impedimento auditivo? Si contesta "sí", explique: ◯ SI ◯ NO

6. ¿Tiene Ud. alguna preocupación sobre la visión de su bebé? Si contesta "sí", explique: ◯ SI ◯ NO

7. ¿Ha tenido su bebé algún problema de salud en los últimos meses? Si contesta "sí", explique: ◯ SI ◯ NO

8. ¿Tiene alguna preocupación sobre el comportamiento de su bebé? Si contesta "sí", explique: ◯ SI ◯ NO

9. ¿Le preocupa algún aspecto del desarrollo de su bebé? Si contesta "sí", explique: ◯ SI ◯ NO

E102120600

ASQ-3: Compilación de datos **12** meses

11 mes 0 días a 12 meses 30 días

Nombre del bebé: _____ Fecha de hoy: _____

de identificación del bebé: _____ Fecha de nacimiento: _____

Nombre del programa/proveedor: _____ Para bebés prematuros, ¿seleccionó el cuestionario apropiado tomando en cuenta la edad ajustada del bebé? ◯ Sí ◯ No

1. CALIFIQUE EL CUESTIONARIO Y PASE EL PUNTAJE TOTAL DE CADA SECCION AL GRAFICO DE ABAJO: Véase *ASQ-3 User's Guide* para obtener más detalles, incluyendo la manera de ajustar el puntaje si faltan respuestas a algunas preguntas. Califique cada pregunta (SI = 10, A VECES = 5, TODAVIA NO = 0). Sume los puntos de cada pregunta, anotando el puntaje total en la línea provista al final de cada sección del cuestionario. En el gráfico de abajo, anote el puntaje total de cada sección, y rellene el círculo correspondiente.

Área	Límite	Puntaje Total	0	5	10	15	20	25	30	35	40	45	50	55	60
Comunicación	15.64		●	●	●	●	○	○	○	○	○	○	○	○	○
Motora gruesa	21.49		●	●	●	●	●	○	○	○	○	○	○	○	○
Motora fina	34.50		●	●	●	●	●	●	●	○	○	○	○	○	○
Resolución de problemas	27.32		●	●	●	●	●	●	○	○	○	○	○	○	○
Socio-individual	21.73		●	●	●	●	●	○	○	○	○	○	○	○	○

2. TRANSFIERA LAS RESPUESTAS DE LA SECCION TITULADA "OBSERVACIONES GENERALES": Las respuestas escritas en negrita o con mayúsculas requerirán un seguimiento. Véase el capítulo 6 del *ASQ-3 User's Guide* para obtener información sobre las pautas a seguir.

1. ¿Usa ambas manos y ambas piernas por igual? Sí **NO**
   Comentarios:
2. ¿Experimenta con sonidos y/o parece formar palabras? Sí **NO**
   Comentarios:
3. ¿Normalmente pone los pies completamente planos en el suelo? Sí **NO**
   Comentarios:
4. ¿Preocupaciones porque no hace sonidos? **SI** No
   Comentarios:
5. Historial: ¿Hay problemas auditivos en la familia? **SI** No
   Comentarios:
6. ¿Preocupaciones sobre la vista? **SI** No
   Comentarios:
7. ¿Hay problemas de salud recientes? **SI** No
   Comentarios:
8. ¿Preocupaciones sobre comportamiento? **SI** No
   Comentarios:
9. ¿Otras preocupaciones? **SI** No
   Comentarios:

3. INTERPRETACION DEL PUNTAJE Y RECOMENDACIONES PARA EL SEGUIMIENTO DEL ASQ: Para determinar el nivel de seguimiento apropiado, hay que tomar en cuenta el *Puntaje total* de cada sección, las respuestas de la sección titulada "Observaciones generales", y también factores adicionales, tales como considerar si el bebé tiene oportunidades para practicar las habilidades.

Si el *Puntaje total* está dentro del área ▭, el puntaje del bebé está por encima de las expectativas, y el desarrollo del bebé parece estar bien hasta ahora.

Si el *Puntaje total* está dentro del área ▬, el puntaje está apenas por encima de las expectativas. Proporcione actividades adicionales para ayudarle al bebé y vigile su progreso.

Si el *Puntaje total* está dentro del área ■, el puntaje está debajo de las expectativas. Quizás se requiera una evaluación adicional más a fondo.

4. SEGUIMIENTO DEL ASQ: Marque todos los que apliquen.

_____ Dar actividades adicionales y reevaluar en _____ meses.

_____ Compartir los resultados con su médico familiar (primary health care provider).

_____ Referirlo/la para una evaluación auditiva, visual, o de comportamiento. (Marque con un círculo todos los que apliquen.)

_____ Referirlo/la a un médico familiar u otra agencia comunitaria (favor de escribir la razón): _____.

_____ Referirlo/la a un programa de intervención temprana/educación especial para niños preescolares para hacer una evaluación adicional.

_____ No tomar medidas adicionales en este momento.

_____ Medida adicional (favor de escribirla): _____ .

5. OPCIONAL: Anote las respuestas específicas (S = SI, V = A VECES, N = TODAVIA NO, R = falta esta respuesta).

	1	2	3	4	5	6
Comunicación						
Motora gruesa						
Motora fina						
Resolución de problemas						
Socio-individual						

P102120700

ANNEX 6: ASQ-3 (24 MONTHS)

ASQ-3™ Ages & Stages Questionnaires®

23 meses 0 días a 25 meses 15 días

Cuestionario de 24 meses

Favor de proveer los siguientes datos. Al completar este formulario, use solamente una pluma de tinta negra o azul y escriba legiblemente con letra de molde.

Fecha en que se completó el cuestionario: D D M M A A A A

Información del niño/a

Nombre del niño/a: | Inicial de su segundo nombre: | Apellido(s) del niño/a:

Fecha de nacimiento del niño/a: D D M M A A A A

Sexo del niño/a: ◯ Masculino ◯ Femenino

Información de la persona que está llenando este cuestionario

Nombre: | Inicial de su segundo nombre: | Apellido(s):

Dirección:

Parentesco con el niño/a: ◯ Padre/madre ◯ Tutor ◯ Maestro/a ◯ Educador/a o asistente de preescolar ◯ Abuelo/a u otro pariente ◯ Madre/padre de acogida ◯ Otro/a:

Ciudad: | Estado/Provincia: | Código postal:

País: | # de teléfono de casa: | Otro # de teléfono:

Su dirección electrónica:

Los nombres de las personas que le están ayudando a llenar este cuestionario:

INFORMACION DEL PROGRAMA

de identificación del niño/a:

de identificación del programa:

Nombre del programa:

E102240100

ASQ-3™

Cuestionario de 24 meses

23 meses 0 días a 25 meses 15 días

En las siguientes páginas Ud. encontrará una serie de preguntas sobre diferentes actividades que generalmente hacen los niños. Puede ser que su niño/a ya pueda hacer algunas de estas actividades, y que todavía no haya realizado otras. Después de leer cada pregunta, por favor marque la respuesta que indique si su niño/a hace la actividad regularmente, a veces, o todavía no.

Puntos que hay que recordar:

- ☑ Asegúrese de intentar cada actividad con su niño/a antes de contestar las preguntas.
- ☑ Complete el cuestionario haciendo las actividades con su niño/a como si fueran un juego divertido.
- ☑ Asegúrese de que su niño/a haya descansado y comido.
- ☑ Por favor, devuelva este cuestionario antes de esta fecha: _____.

Notas:

_____

_____

_____

_____

_____

A esta edad, muchos niños no cooperan cuando se les pide hacer cosas. Quizás Ud. tenga que intentar hacer las actividades más de una vez con su niño/a. Si es posible, intente hacer las actividades cuando su niño/a tenga buena disposición. Si su niño/a puede hacer la actividad, pero se niega a hacerla, marque "sí" en la pregunta.

COMUNICACION

	SI	A VECES	TODAVIA NO	
1. Sin enseñarle primero, ¿puede *señalar con el dedo* el dibujo correcto cuando Ud. le dice, "Enséñame dónde está el gatito", o le pregunta, "¿Dónde está el perro?" *(Solamente tiene que identificar un dibujo correctamente.)*	◯	◯	◯	___
2. ¿Imita su niña una oración de dos palabras? Por ejemplo, cuando Ud. dice "Mamá juega", "Papá come", o "¿Qué es?", repite ella la misma frase? *(Marque "sí" aun si sus palabras sean difíciles de entender.)*	◯	◯	◯	___
3. Sin darle pistas señalándole o usando gestos, ¿puede su niño seguir al menos *tres* de las siguientes instrucciones?	◯	◯	◯	___
◯ a. "Pon el juguete en la mesa". ◯ b. "Cierra la puerta". ◯ c. "Tráeme una toalla". ◯ d. "Busca tu abrigo". ◯ e. "Dame la mano". ◯ f. "Agarra tu libro".				
4. Si Ud. señala un dibujo de una pelota (gatito, vaso, gorro, etc.) y le pregunta a su niña "¿qué es?", ¿puede *identificar y nombrar* al menos un dibujo?	◯	◯	◯	___
5. ¿Puede decir dos o tres palabras juntas que representen ideas diferentes, como: "Veo perro", "Mamá llega casa", o "¿Se fue gatito"? *(No cuente las combinaciones de palabras que expresen una sóla idea como "se acabó", "está bien", y "¿qué es?")* Escriba un ejemplo de una combinación de palabras que dice su niño:	◯	◯	◯	___

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COMUNICACION *(continuación)*

	SI	A VECES	TODAVIA NO	
6. ¿Puede usar correctamente al menos dos palabras como "mi", "yo", "mía", o "tú"?	◯	◯	◯	___

TOTAL EN COMUNICACION ___

MOTORA GRUESA

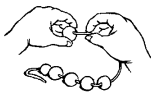
	SI	A VECES	TODAVIA NO	
1. ¿Su niño puede bajar las escaleras si usted lo lleva de la mano? Puede agarrarse de la pared o de la barandilla también. *(Ud. puede hacer esta observación en la tienda, en el parque, o en casa.)*	◯	◯	◯	___
2. Al enseñarle cómo se da una patada a un balón, ¿intenta su niño dar la patada moviendo la pierna hacia adelante o caminando hasta tocar el balón? *(Si ya sabe dar una patada al balón, marque "sí" en esta pregunta.)* 	◯	◯	◯	___
3. ¿Su niño sube o baja al menos dos escalones sin ayuda? Puede agarrarse de la pared o de la barandilla. 	◯	◯	◯	___
4. ¿Su niña corre bien y sabe detenerse sin chocar con las cosas o caerse? 	◯	◯	◯	___
5. ¿Puede saltar su niño, levantando ambos pies del suelo a la vez? 	◯	◯	◯	___
6. Sin apoyarse en ningún objeto, ¿sabe su niño dar una patada a un balón moviendo la pierna hacia atrás y luego hacia adelante?* 	◯	◯	◯	___ *

TOTAL EN MOTORA GRUESA ___

**Si marcó "sí" o "a veces" en la pregunta 6, marque "sí" en la pregunta 2.*

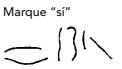
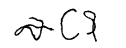
E102240300

MOTORA FINA

	SI	A VECES	TODAVIA NO	
1. Normalmente, ¿puede su niño meterse la cuchara en la boca sin que se le caiga la comida?	◯	◯	◯	___
2. ¿Sabe darle la vuelta a las hojas de un libro sin ayuda? *(Tal vez pase más de una hoja a la vez.)*	◯	◯	◯	___
3. ¿Rota (gira) la mano su niña al intentar abrir una puerta, darle cuerda a un juguete, jugar con un trompo, o poner y quitar una tapa de un frasco?	◯	◯	◯	___
4. ¿Su niño prende y apaga interruptores (como el de la luz)?	◯	◯	◯	___
5. ¿Puede su niña poner siete cubitos o juguetes uno sobre otro sin ayuda? *(También puede usar carretes de hilo, cajitas, o juguetes que midan aproximadamente 1 pulgada, o 3 centímetros.)*	◯	◯	◯	___
6. ¿Sabe meter un cordón (o agujeta) por el agujero de objetos pequeños como cuentas de madera, sopa de macarrones o de rueditas, o por los agujeros de los zapatos? 	◯	◯	◯	___

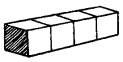
TOTAL EN MOTORA FINA ___

RESOLUCION DE PROBLEMAS

	SI	A VECES	TODAVIA NO	
1. Después de observarlo/la a Ud. dibujar una línea de arriba a abajo usando una crayola (o pluma o lápiz), ¿su niño intenta dibujar una línea recta en ***cualquier dirección*** en la hoja de papel? *(Marque "todavía no" si su niño hace rayas o garabatos de un lado para otro.)* Marque "sí"  Marque "todavía no" 	◯	◯	◯	___
2. Después de dejar caer una migaja o un Cheerio (cereal de desayuno) en una pequeña botella transparente, ¿pone la botella al revés para sacarlo? *(No le muestre cómo hacerlo.) (Puede usar una botella de refresco o un biberón.)*	◯	◯	◯	___
3. ¿Su niña juega con objetos imaginándose que son otras cosas? Por ejemplo, ¿se pone un vaso junto a la oreja jugando como si fuera un teléfono? ¿Se pone una caja en la cabeza como si fuera un gorro? ¿Usa un cubito u otro juguete pequeño para revolver la comida?	◯	◯	◯	___
4. ¿Guarda su niño las cosas en el sitio apropiado? Por ejemplo, ¿sabe que sus juguetes deben estar en el estante, que su cobija se pone en la cama, y que los platos se ponen en la cocina?	◯	◯	◯	___
5. Si quiere algo que no alcanza, ¿busca su niña una silla o una caja para subirse encima y alcanzarlo (por ejemplo, para agarrar un juguete que está en el mostrador de la cocina o para "ayudarle" en la cocina)?	◯	◯	◯	___

E102240400

RESOLUCION DE PROBLEMAS *(continuación)*

	SI	A VECES	TODAVIA NO	
6. Mientras su niño lo/la observa, ponga cuatro objetos, como unos cubos o unos carritos, en línea recta. ¿Lo/la intenta imitar poniendo al menos *cuatro* objetos en línea recta? *(También puede usar carretes de hilo, unas cajitas, u otros juguetes.)* 	◯	◯	◯	___

TOTAL EN RESOLUCION DE PROBLEMAS ___

SOCIO-INDIVIDUAL

	SI	A VECES	TODAVIA NO	
1. ¿Sabe su niño beber de un vaso y bajarlo nuevamente sin que se le caiga mucho del contenido?	◯	◯	◯	___
2. ¿Lo/la imita a Ud. su niña, haciendo las mismas actividades que Ud. hace, por ejemplo limpiar algo que se le ha caído, pasar la aspiradora, afeitarse, o peinarse?	◯	◯	◯	___
3. ¿Come con un tenedor?	◯	◯	◯	___
4. Al jugar con un animalito de peluche o con una muñeca, ¿lo mece, le da de comer, le cambia los pañales, lo acuesta, etc.?	◯	◯	◯	___
5. ¿Su niño empuja un carrito con ruedas, un cochecito de bebé, u otro juguete con ruedas, evitando chocar con las cosas y saliéndose en reversa de un rincón si no puede girar?	◯	◯	◯	___
6. ¿Su niña se refiere a sí misma diciendo "yo" más que su propio nombre? Por ejemplo, suele decir "yo lo hago" en lugar de "Susana lo hace".	◯	◯	◯	___

TOTAL EN SOCIO-INDIVIDUAL ___

OBSERVACIONES GENERALES

Los padres y proveedores pueden utilizar el espacio después de cada pregunta para hacer comentarios adicionales.

1. ¿Cree Ud. que su niño/a oye bien? Si contesta "no", explique: ◯ SI ◯ NO

2. ¿Cree Ud. que su niño/a habla igual que los otros niños de su edad? Si contesta "no", explique: ◯ SI ◯ NO

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OBSERVACIONES GENERALES *(continuación)*

3. ¿Puede Ud. entender casi todo lo que dice su niño/a? Si contesta "no", explique: ◯ SI ◯ NO

4. ¿Cree Ud. que su niño/a camina, corre, y trepa igual que los otros niños de su edad? Si contesta "no", explique: ◯ SI ◯ NO

5. ¿Tiene algún familiar con historia de sordera o cualquier otro impedimento auditivo? Si contesta "sí", explique: ◯ SI ◯ NO

6. ¿Tiene Ud. alguna preocupación sobre la visión de su niño/a? Si contesta "sí", explique: ◯ SI ◯ NO

7. ¿Ha tenido su niño/a algún problema de salud en los últimos meses? Si contesta "sí", explique: ◯ SI ◯ NO

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OBSERVACIONES GENERALES *(continuación)*

8. ¿Tiene alguna preocupación sobre el comportamiento de su niño/a? Si contesta "sí", explique: ◯ SI ◯ NO

9. ¿Le preocupa algún aspecto del desarrollo de su niño/a? Si contesta "sí", explique: ◯ SI ◯ NO

E102240700

ASQ-3: Compilación de datos **24** meses

23 meses 0 días a 25 meses 15 días

Nombre del niño/a: _____ Fecha de hoy: _____

de identificación del niño/a: _____ Fecha de nacimiento: _____

Nombre del programa/proveedor: _____

1. **CALIFIQUE EL CUESTIONARIO Y PASE EL PUNTAJE TOTAL DE CADA SECCION AL GRAFICO DE ABAJO:** Véase *ASQ-3 User's Guide* para obtener más detalles, incluyendo la manera de ajustar el puntaje si faltan respuestas a algunas preguntas. Califique cada pregunta (SI = 10, A VECES = 5, TODAVIA NO = 0). Sume los puntos de cada pregunta, anotando el puntaje total en la línea provista al final de cada sección del cuestionario. En el gráfico de abajo, anote el puntaje total de cada sección, y rellene el círculo correspondiente.

Área	Límite	Puntaje Total	0	5	10	15	20	25	30	35	40	45	50	55	60
Comunicación	25.17		●	●	●	●	●	●	○	○	○	○	○	○	○
Motora gruesa	38.07		●	●	●	●	●	●	●	●	○	○	○	○	○
Motora fina	35.16		●	●	●	●	●	●	●	○	○	○	○	○	○
Resolución de problemas	29.78		●	●	●	●	●	●	○	○	○	○	○	○	○
Socio-individual	31.54		●	●	●	●	●	●	●	○	○	○	○	○	○

2. **TRANSFIERA LAS RESPUESTAS DE LA SECCION TITULADA "OBSERVACIONES GENERALES":** Las respuestas escritas en negrita o con mayúsculas requerirán un seguimiento. Véase el capítulo 6 del *ASQ-3 User's Guide* para obtener información sobre las pautas a seguir.

1. ¿Oye bien? Sí **NO**
   Comentarios:
2. ¿Habla como otros niños de su edad? Sí **NO**
   Comentarios:
3. ¿Ud. entiende lo que dice su niño/a? Sí **NO**
   Comentarios:
4. ¿Camina, corre, y trepa como otros niños? Sí **NO**
   Comentarios:
5. Historial: ¿Hay problemas auditivos en la familia? **SI** No
   Comentarios:
6. ¿Preocupaciones sobre la vista? **SI** No
   Comentarios:
7. ¿Hay problemas de salud recientes? **SI** No
   Comentarios:
8. ¿Preocupaciones sobre comportamiento? **SI** No
   Comentarios:
9. ¿Otras preocupaciones? **SI** No
   Comentarios:

3. **INTERPRETACION DEL PUNTAJE Y RECOMENDACIONES PARA EL SEGUIMIENTO DEL ASQ:** Para determinar el nivel de seguimiento apropiado, hay que tomar en cuenta el *Puntaje total* de cada sección, las respuestas de la sección titulada "Observaciones generales", y también factores adicionales, tales como considerar si el niño/a tiene oportunidades para practicar las habilidades.

Si el *Puntaje total* está dentro del área ▭, el puntaje del niño/a está por encima de las expectativas, y el desarrollo del niño/a parece estar bien hasta ahora.

Si el *Puntaje total* está dentro del área ▬, el puntaje está apenas por encima de las expectativas. Proporcione actividades adicionales para ayudarle al niño/a y vigile su progreso.

Si el *Puntaje total* está dentro del área ■, el puntaje está debajo de las expectativas. Quizás se requiera una evaluación adicional más a fondo.

4. **SEGUIMIENTO DEL ASQ:** Marque todos los que apliquen.

_____ Dar actividades adicionales y reevaluar en _____ meses.

_____ Compartir los resultados con su médico familiar (primary health care provider).

_____ Referirlo/la para una evaluación auditiva, visual, o de comportamiento. (Marque con un círculo todos los que apliquen.)

_____ Referirlo/la a un médico familiar u otra agencia comunitaria (favor de escribir la razón): _____.

_____ Referirlo/la a un programa de intervención temprana/educación especial para niños preescolares para hacer una evaluación adicional.

_____ No tomar medidas adicionales en este momento.

_____ Medida adicional (favor de escribirla): _____ .

5. **OPCIONAL:** Anote las respuestas específicas (S = SI, V = A VECES, N = TODAVIA NO, R = falta esta respuesta).

	1	2	3	4	5	6
Comunicación						
Motora gruesa						
Motora fina						
Resolución de problemas						
Socio-individual						

P102240800

ANNEX 7: ASQ-3 (42 MONTHS)

ASQ-3 Ages & Stages Questionnaires®

39 meses 0 días a 44 meses 30 días

Cuestionario de 42 meses

Favor de proveer los siguientes datos. Al completar este formulario, use solamente una pluma de tinta negra o azul y escriba legiblemente con letra de molde.

Fecha en que se completó el cuestionario: _____

Información del niño/a:

Nombre del niño/a: _____ Inicial de su segundo nombre: _____ Apellido(s) del niño/a: _____

Sexo del niño/a:
◯ Masculino ◯ Femenino

Fecha de nacimiento del niño/a: _____

Información de la persona que está llenando este cuestionario

Nombre: _____ Inicial de su segundo nombre: _____ Apellido(s): _____

Parentesco con el niño/a:
◯ Padre/madre ◯ Tutor ◯ Maestro/a ◯ Educador/a o asistente de preescolar
◯ Abuelo/a u otro pariente ◯ Madre/padre de acogida ◯ Otro/a: _____

Dirección: _____

Ciudad: _____ Estado/ Provincia: _____ Código postal: _____

País: _____ # de teléfono de casa: _____ Otro # de teléfono: _____

Su dirección electrónica: _____

Los nombres de las personas que le están ayudando a llenar este cuestionario: _____

_____

Información del programa

de identificación del niño/a: _____

de identificación del programa: _____

Nombre del programa: _____

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ASQ-3™

Cuestionario de 42 meses

39 meses 0 días a 44 meses 30 días

En las siguientes páginas Ud. encontrará una serie de preguntas sobre diferentes actividades que generalmente hacen los niños. Puede ser que su niño/a ya pueda hacer algunas de estas actividades, y que todavía no haya realizado otras. Después de leer cada pregunta, por favor marque la respuesta que indique si su niño/a hace la actividad regularmente, a veces, o todavía no.

Puntos que hay que recordar:

- ☑ Asegúrese de intentar cada actividad con su niño/a antes de contestar las preguntas.
- ☑ Complete el cuestionario haciendo las actividades con su niño/a como si fueran un juego divertido.
- ☑ Asegúrese de que su niño/a haya descansado y comido.
- ☑ Por favor, devuelva este cuestionario antes de esta fecha: _____.

Notas:

_____

_____

_____

_____

_____

COMUNICACION

	SI	A VECES	TODAVIA NO	
1. Sin darle pistas ni señas, ni hacer gestos, dígale a su niño: "Pon el libro ***encima de*** la mesa y pon el zapato ***debajo de*** la silla". ¿Puede seguir las dos instrucciones correctamente?	◯	◯	◯	___
2. Al mirar un libro de ilustraciones, ¿puede su niña decirle lo que pasa en la ilustración o nombrar la actividad que se muestra (por ejemplo, "ladra", "come", "corre", o "llora")? Ud. puede preguntarle, "¿Qué hace el perro (o el niño)?"	◯	◯	◯	___
3. Enséñele a su niño como el cierre (cremallera) de un abrigo sube y baja y dígale: "Mira, esto sube y baja". Suba el cierre hasta la mitad y pídale que lo ***baje***. Suba el cierre hasta la mitad otra vez y pídale que lo ***suba***. Repita esto varias veces antes de pedirle que lo haga solo. ¿Siempre sube el cierre cuando Ud. le dice "súbelo" y siempre lo baja al decirle "bájalo"?	◯	◯	◯	___
4. Al preguntarle a su niña, "¿Cómo te llamas?" ¿responde diciendo su nombre y apellido?	◯	◯	◯	___
5. Sin hacer señas para ayudarle ni repetir las instrucciones, ¿puede su niño llevar a cabo tres acciones ***completamente diferentes*** cuando Ud. se lo pide? Debe decirle las tres instrucciones antes de que él comience a hacerlas. Por ejemplo, le puede pedir, "Aplaude con las manos, camina hasta la puerta, y siéntate", o "Dame la pluma, abre el libro, y ponte de pie".	◯	◯	◯	___
6. Al formar oraciones, ¿incluye su niña todas las palabras necesarias (como "un", "el", "la", "soy", "es", "está", y "son") para que sean completas? Por ejemplo dice: "Voy ***al*** parque", "¿Dónde ***está*** el juguete?" o "¿Vas ***a*** venir también?"	◯	◯	◯	___

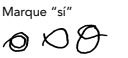
TOTAL EN COMUNICACION ___

MOTORA GRUESA

		SI	A VECES	TODAVIA NO	
1.	¿Sube las escaleras su niño poniendo sólo un pie en cada escalón? *(El pie izquierdo en un escalón y el derecho en el siguiente.)* Puede agarrarse de la barandilla o de la pared. *(Ud. puede hacer esta observación en lugares como una tienda, el parque, o en casa.)* 	○	○	○	___
2.	¿Puede pararse su niña en un solo pie por aproximadamente 1 segundo sin agarrarse de nada? 	○	○	○	___
3.	Al estar de pie, ¿su niño lanza una pelota hacia adelante, *levantando el brazo* a la altura del hombro? *(Marque "todavía no" si la deja caer o si la tira desde la altura de la cintura.)* 	○	○	○	___
4.	¿Salta su niña hacia adelante con los dos pies juntos al menos 6 pulgadas (o 15 centímetros)? 	○	○	○	___
5.	Cuando Ud. le lanza una pelota grande, ¿su niño la agarra con las dos manos? *(Ud. debe situarse a unos 5 pies, o 1.5 metros, de su niño y darle dos o tres oportunidades para hacer la actividad antes de marcar la respuesta.)* 	○	○	○	___
6.	En el parque infantil, ¿puede su niña subir los escalones de la resbaladilla para llegar a lo alto y después deslizarse sin ayuda?	○	○	○	___

TOTAL EN MOTORA GRUESA ___

MOTORA FINA

		SI	A VECES	TODAVIA NO	
1.	Después de observarlo/la a Ud. dibujar un círculo, pídale a su niño que dibuje un círculo como el suyo. No lo deje dibujar encima del suyo ni usar papel transparente. ¿Su niño dibuja un círculo, copiando lo que Ud. hizo? Marque "sí"  Marque "todavía no" 	○	○	○	___

MOTORA FINA *(continuación)*

	SI	A VECES	TODAVIA NO	

2. Después de observarlo/la a Ud. dibujar una línea de un lado al otro de la hoja de papel, pídale a su niña que haga una línea como la suya. No la deje dibujar encima de la suya ni usar papel transparente. ¿Su niña dibuja una línea horizontal, copiando lo que Ud. hizo?

○ ○ ○ ___

3. ¿Su niño intenta cortar papel con tijeras para niños? No es necesario que llegue a cortar el papel, pero sí debe saber abrir y cerrar las tijeras mientras que agarra el papel con la otra mano. *(Ud. puede enseñarle cómo se usan las tijeras. Asegúrese de supervisar a su niño cuando esté usando las tijeras para que no se vaya a cortar.)*

○ ○ ○ ___

4. Al hacer un dibujo, ¿sujeta el lápiz, la crayola, o la pluma con los dedos y el pulgar como lo hace un adulto?

○ ○ ○ ___

5. ¿Puede armar un rompecabezas de cinco a siete piezas que se conectan entre sí? *(Si Ud. no tiene disponible un rompecabezas, tome una fotografía grande de una revista y córtela en 6 piezas.)* ¿Puede reconstruir la imagen, juntando las piezas?

○ ○ ○ ___

6. Muéstrele a su niña la figura de la derecha. ¿Puede ella copiarla en una hoja de papel grande con un lápiz, una crayola, o una pluma, sin trazarla por encima? (El dibujo de su niña debe verse como la figura, excepto que puede ser de tamaño diferente.)

○ ○ ○ ___

TOTAL EN MOTORA FINA ___

RESOLUCION DE PROBLEMAS

	SI	A VECES	TODAVIA NO	

1. Al señalarle esta figura y preguntarle a su niño, "¿Qué es?", ¿dice una palabra que se refiera a una persona o a un ser que se parezca a una persona? *(Marque "sí" si da una respuesta como "muñeco de nieve", "niño", "señor", "niña", "papá", "astronauta", o "mono".)* Escriba la respuesta de su niño a continuación:

○ ○ ○ ___

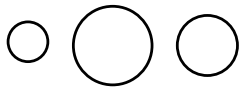
2. Si Ud. le dice a su niña, "Di 'siete tres'", ¿repite *únicamente* los dos números en el mismo orden? *Ud. no debe repetir los números.* Si es necesario, intente otro par de números, por ejemplo, "Di 'ocho dos'". *(Su niña sólo tiene que repetir una serie de dos números para que Ud. pueda marcar "sí" en esta pregunta.)*

○ ○ ○ ___

3. Muéstrele a su niño cómo hacer un puente con cubos, cajas, o latas como el del dibujo. ¿Su niño lo/la imita haciendo un puente que se parece al de Ud.?

○ ○ ○ ___

RESOLUCION DE PROBLEMAS *(continuación)*

	SI	A VECES	TODAVIA NO	
4. Si Ud. le dice a su niña: "Di 'cinco, ocho, tres'", ¿repite ella ***únicamente*** los tres números en el mismo orden? ***Ud. no debe repetir los números.*** Si es necesario, intente otra serie de números, por ejemplo, "Di 'siete, nueve, dos'". *(Su niña sólo tiene que repetir una serie de tres números para que Ud. pueda marcar "sí" en esta pregunta.)*	○	○	○	___
5. Si Ud. le pregunta, "Cuál círculo es el más pequeño?" ¿apunta su niño al círculo correcto? *(Haga esta pregunta sin ayudarle a través de señas o gestos que le puedan indicar cuál es el círculo más pequeño.)* 	○	○	○	___
6. ¿Se disfraza y actúa imaginando ser alguien o algo diferente? Por ejemplo, se viste con ropa diferente y se imagina que es la mamá, el papá, el hermano, la hermana, un animal, o cualquier otro ser imaginario?	○	○	○	___

TOTAL EN RESOLUCION DE PROBLEMAS ___

SOCIO-INDIVIDUAL

	SI	A VECES	TODAVIA NO	
1. Si Ud. le pregunta a su niña, "¿Quién está ahí?" cuando se ve en el espejo, ¿contesta "yo" o dice su nombre?	○	○	○	___
2. ¿Su niño se pone el abrigo, su chaqueta, o su camisa sin ayuda?	○	○	○	___
3. Hágale la siguiente pregunta a su niña empleando estas palabras exactas: "¿Eres una niña o un niño?" ¿Sabe responder correctamente?	○	○	○	___
4. ¿Puede esperar su turno su niño, respetando el turno de los otros niños o adultos?	○	○	○	___
5. ¿Usa cubiertos para servirse comida, sacándola de un recipiente y poniéndola en otro? Por ejemplo, ¿su niña puede usar una cuchara grande para sacar puré de manzana de un recipiente y ponerlo en un plato hondo?	○	○	○	___
6. ¿Se lava las manos con agua y jabón y después se seca sin ayuda?	○	○	○	___

TOTAL EN SOCIO-INDIVIDUAL ___

OBSERVACIONES GENERALES

Los padres y proveedores pueden utilizar el espacio después de cada pregunta para hacer comentarios adicionales.

1. ¿Cree Ud. que su niño/a oye bien? Si contesta "no", explique: ○ SI ○ NO

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OBSERVACIONES GENERALES *(continuación)*

2. ¿Cree Ud. que su niño/a habla igual que los otros niños de su edad? Si contesta "no", explique: ◯ SI ◯ NO

3. ¿Puede Ud. entender casi todo lo que dice su niño/a? Si contesta "no", explique: ◯ SI ◯ NO

4. ¿Otras personas pueden entender la mayor parte de lo que dice su niño/a? Si contesta "no", explique: ◯ SI ◯ NO

5. ¿Cree Ud. que su niño/a camina, corre, y trepa igual que los otros niños de su edad? Si contesta "no", explique: ◯ SI ◯ NO

6. ¿Tiene algún familiar con historia de sordera o cualquier otro impedimento auditivo? Si contesta "sí", explique: ◯ SI ◯ NO

7. ¿Tiene Ud. alguna preocupación sobre la visión de su niño/a? Si contesta "sí", explique: ◯ SI ◯ NO

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OBSERVACIONES GENERALES *(continuación)*

8. ¿Ha tenido su niño/a algún problema de salud en los últimos meses? Si contesta "sí", explique: ◯ SI ◯ NO

9. ¿Tiene alguna preocupación sobre el comportamiento de su niño/a? Si contesta "sí", explique: ◯ SI ◯ NO

10. ¿Le preocupa algún aspecto del desarrollo de su niño/a? Si contesta "sí", explique: ◯ SI ◯ NO

ASQ-3: Compilación de datos **42** meses

39 meses 0 días a 44 meses 30 días

Nombre del niño/a: _____ Fecha de hoy: _____

de identificación del niño/a: _____ Fecha de nacimiento: _____

Nombre del programa/proveedor: _____

1. **CALIFIQUE EL CUESTIONARIO Y PASE EL PUNTAJE TOTAL DE CADA SECCION AL GRAFICO DE ABAJO:** Véase *ASQ-3 User's Guide* para obtener más detalles, incluyendo la manera de ajustar el puntaje si faltan respuestas a algunas preguntas. Califique cada pregunta (SI = 10, A VECES = 5, TODAVIA NO = 0). Sume los puntos de cada pregunta, anotando el puntaje total en la línea provista al final de cada sección del cuestionario. En el gráfico de abajo, anote el puntaje total de cada sección, y rellene el círculo correspondiente.

Área	Límite	Puntaje Total	0	5	10	15	20	25	30	35	40	45	50	55	60
Comunicación	27.06		●	●	●	●	●	●	○	○	○	○	○	○	○
Motora gruesa	36.27		●	●	●	●	●	●	●	●	○	○	○	○	○
Motora fina	19.82		●	●	●	●	○	○	○	○	○	○	○	○	○
Resolución de problemas	28.11		●	●	●	●	●	●	○	○	○	○	○	○	○
Socio-individual	31.12		●	●	●	●	●	●	●	○	○	○	○	○	○

2. **TRANSFIERA LAS RESPUESTAS DE LA SECCION TITULADA "OBSERVACIONES GENERALES":** Las respuestas escritas en negrita o con mayúsculas requerirán un seguimiento. Véase el capítulo 6 del *ASQ-3 User's Guide* para obtener información sobre las pautas a seguir.

1. ¿Oye bien? Sí **NO**
   Comentarios:
2. ¿Habla como otros niños de su edad? Sí **NO**
   Comentarios:
3. ¿Ud. entiende lo que dice su niño/a? Sí **NO**
   Comentarios:
4. ¿Otras personas entienden lo que dice su niño/a? Sí **NO**
   Comentarios:
5. ¿Camina, corre, y trepa como otros niños? Sí **NO**
   Comentarios:
6. Historial: ¿Hay problemas auditivos en la familia? **SI** No
   Comentarios:
7. ¿Preocupaciones sobre la vista? **SI** No
   Comentarios:
8. ¿Hay problemas de salud recientes? **SI** No
   Comentarios:
9. ¿Preocupaciones sobre comportamiento? **SI** No
   Comentarios:
10. ¿Otras preocupaciones? **SI** No
    Comentarios:

3. **INTERPRETACION DEL PUNTAJE Y RECOMENDACIONES PARA EL SEGUIMIENTO DEL ASQ:** Para determinar el nivel de seguimiento apropiado, hay que tomar en cuenta el *Puntaje total* de cada sección, las respuestas de la sección titulada "Observaciones generales", y también factores adicionales, tales como considerar si el niño/a tiene oportunidades para practicar las habilidades.

Si el *Puntaje total* está dentro del área ▭, el puntaje del niño/a está por encima de las expectativas, y el desarrollo del niño/a parece estar bien hasta ahora.
Si el *Puntaje total* está dentro del área ▬, el puntaje está apenas por encima de las expectativas. Proporcione actividades adicionales para ayudarle al niño/a y vigile su progreso.
Si el *Puntaje total* está dentro del área ■, el puntaje está debajo de las expectativas. Quizás se requiera una evaluación adicional más a fondo.

4. **SEGUIMIENTO DEL ASQ:** Marque todos los que apliquen.

_____ Dar actividades adicionales y reevaluar en _____ meses.
_____ Compartir los resultados con su médico familiar (primary health care provider).
_____ Referirlo/la para una evaluación auditiva, visual, o de comportamiento. (Marque con un círculo todos los que apliquen.)
_____ Referirlo/la a un médico familiar u otra agencia comunitaria (favor de escribir la razón): _____.
_____ Referirlo/la a un programa de intervención temprana/educación especial para niños preescolares para hacer una evaluación adicional.
_____ No tomar medidas adicionales en este momento.
_____ Medida adicional (favor de escribirla): _____ .

5. **OPCIONAL:** Anote las respuestas específicas (S = SI, V = A VECES, N = TODAVIA NO, R = falta esta respuesta).

	1	2	3	4	5	6
Comunicación						
Motora gruesa						
Motora fina						
Resolución de problemas						
Socio-individual						

P102420800

ANNEX 8: DATA COLLECTION SHEET

DOCUMENTO DE RECOGIDA DE DATOS

Nombre del estudio: Protocolo para la implementación de la resucitación neonatal con cordón íntegro en sala de partos.

Centro asistencial:

Responsables de la recogida:

Código de paciente: _____

Grupo de intervención: 1 ☐ / 2 ☐

DATOS RECOGIDOS

En cada sección del documento se deben anotar los datos indicados en las unidades indicadas. Cada profesional debe especificar los apartados que son su responsabilidad.

Aquellos datos que sea posible recoger tras el nacimiento (después de la intervención) serán anotados en ese momento. El resto de información será recopilada durante la estancia hospitalaria y anotada en este documento tras el alta domiciliaria del paciente (o bien su deceso en caso de ocurrir este).

La información del neurodesarrollo será documentada tras cada consulta.

1. **Información general:**
    - **Edad gestacional:** _____ semanas
    - **Crecimiento fetal:** RCIU ☐ / PEG ☐ / AEG ☐ / GEG ☐
2. **Información prenatal:**
    - **Sensibilización Rh gestante (Coombs Directo):** Positivo ☐ / Negativo ☐
    - **Diabetes (gestante):** Si ☐ / No ☐
    - **Hipertensión (gestante):** Si ☐ / No ☐

- **Infección (gestante):** Si ☐ / No ☐
- **Anomalías congénitas fetales:** Si ☐ / No ☐

3. **Información perinatal:**

- **Tipo de parto:** Vaginal ☐ / Instrumentado ☐ / Cesárea ☐
- **Duración del parto:** _____ : _____ h
- **Ruptura de membranas:** Espontánea ☐ / Prematura ☐ / Artificial ☐
- **Complicaciones durante el parto:** Si ☐ / No ☐
- **Administración de corticoides:** Si ☐ / No ☐
- **Administración de sulfato de magnesio:** Si ☐ / No ☐
- **Puntuación Apgar:** 1 minuto _____ / 5 minutos _____ / 10 minutos _____
- **pH de cordón umbilical:** 5 minutos _____ / 20 minutos _____
- **Tiempo de establecimiento ventilatorio:** _____ minutos
- **Uso de medicación durante la reanimación:** Si ☐ / No ☐

4. **Información postnatal:**

- **Presión arterial media:**
  - 4h : _____ mmHg
  - 8h: _____ mmHg
  - 12h: _____ mmHg
  - 16h: _____ mmHg
  - 20h: _____ mmHg
  - 24h: _____ mmHg
  - 28h: _____ mmHg
  - 32h: _____ mmHg
  - 36h: _____ mmHg
  - 40h: _____ mmHg
  - 44h: _____ mmHg
  - 48h: _____ mmHg
  - 52h: _____ mmHg
  - 56h: _____ mmHg
  - 60h: _____ mmHg
  - 64h: _____ mmHg
  - 70h: _____ mmHg

- **Parámetros sépticos:**

Procalcitonina	Proteína C Reactiva
• 1 dv: _____ ng/mL • 2 ddv: _____ ng/mL • 3 ddv: _____ ng/mL • 4 ddv: _____ ng/mL • 5 ddv: _____ ng/mL • 6 ddv: _____ ng/mL • 7 ddv: _____ ng/mL	• 1 dv: _____ µg/mL • 2 ddv: _____ µg/mL • 3 ddv: _____ µg/mL • 4 ddv: _____ µg/mL • 5 ddv: _____ µg/mL • 6 ddv: _____ µg/mL • 7 ddv: _____ µg/mL

- **Parámetros hemáticos:**

Hemoglobina	Hematocrito
• 1 dv: _____ g/dL • 2 ddv: _____ g/dL • 3 ddv: _____ g/dL • 4 ddv: _____ g/dL • 5 ddv: _____ g/dL • 6 ddv: _____ g/dL • 7 ddv: _____ g/dL	• 1 dv: _____ % • 2 ddv: _____ % • 3 ddv: _____ % • 4 ddv: _____ % • 5 ddv: _____ % • 6 ddv: _____ % • 7 ddv: _____ %

- **Complicaciones**
    - Síndrome de distrés respiratorio: Si ☐ / No ☐
    - Hemorragia intraventricular: No HIV ☐ / Leve HIV ☐ / Severa HIV ☐
    - Enterocolitis necrotizante: Si ☐ / No ☐
    - Sepsis precoz: Si ☐ / No ☐
    - Sepsis tardía: Si ☐ / No ☐

- **Supervivencia:** Vivo ☐ / Fallecido ☐

5. **Neurodesarrollo:**

- **ASQ-3 (6 meses):**
    - Comunicación: _____ puntos
    - Motora gruesa: _____ puntos
    - Motora fina: _____ puntos
    - Resolución de problemas: _____ puntos
    - Socio-individual: _____ puntos
    - Observaciones generales:

    En este apartado el profesional encargado anotará si existe alguna respuesta alterada en las preguntas tituladas como "OBSERVACIONES GENERALES" del cuestionario ASQ-3.

- **ASQ-3 (12 meses):**
    - Comunicación: _____ puntos
    - Motora gruesa: _____ puntos
    - Motora fina: _____ puntos
    - Resolución de problemas: _____ puntos
    - Socio-individual: _____ puntos
    - Observaciones generales:

    En este apartado el profesional encargado anotará si existe alguna respuesta alterada en las preguntas tituladas como "OBSERVACIONES GENERALES" del cuestionario ASQ-3.

- **ASQ-3 (24 meses):**
    - Comunicación: _____ puntos
    - Motora gruesa: _____ puntos
    - Motora fina: _____ puntos
    - Resolución de problemas: _____ puntos
    - Socio-individual: _____ puntos
    - Observaciones generales:

      En este apartado el profesional encargado anotará si existe alguna respuesta alterada en las preguntas tituladas como "OBSERVACIONES GENERALES" del cuestionario ASQ-3.

- **ASQ-3 (42 meses):**
    - Comunicación: _____ puntos
    - Motora gruesa: _____ puntos
    - Motora fina: _____ puntos
    - Resolución de problemas: _____ puntos
    - Socio-individual: _____ puntos
    - Observaciones generales:

      En este apartado el profesional encargado anotará si existe alguna respuesta alterada en las preguntas tituladas como "OBSERVACIONES GENERALES" del cuestionario ASQ-3.