

COMPARISON OF TWO INTUBATION PROCEDURE IN NEONATES: RESIDENTS ASSISTED BY VIDEO- LARYNGOSCOPY VERSUS NEONATOLOGIST USING DIRECT LARYNGOSCOPY

A non-inferiority, multicenter, open-labelled clinical trial.

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1 ABBREVIATIONS

DL= Direct laryngoscope

ET= Endotracheal tube

NICU= Neonatology intensive care unit

EI= Endotracheal intubation.

NN= Neonates

VL= Video-laryngoscope

2 ABSTRACT

Background: Neonatal intubation is an important procedure that neonatologist do in NICU and is fundamental that everyone knows how to perform it. However, this procedure has difficulties and risks. Neonates (NN) is very vulnerable group of patients in a hospital and often they have many complications during endotracheal intubation (EI). Throughout the years, technology has developed to improve the techniques used during clinical practice, but EI is a skill that has been used less and less. A recent review shows that if there is a previous EI training we can improve the intubation skill in less experienced professionals.

Objective: To analyze the complication rate using VL by a resident versus direct laryngoscopy (DL) by a neonatologist in a NN intubation.

Methods: the design is a non-inferiority, prospective, multicenter, randomized, open-labelled, parallel-group trial. We will enroll 1462 patients during 1 year from 13 Spanish hospitals. These patients will be randomized into two group, 731 EI will be done by a neonatologist with direct laryngoscopy (DL) and the other 731 will be done by a resident with video-laryngoscopy (VL).

Main outcomes complication rate during the intervention. The analysis of response to treatment for endpoint variable (complication rate) between independent treatment and control groups (main objective of the proposal) will be performed by a lineal regression analysis

Keywords: neonates, video-laryngoscopy, direct laryngoscopy, intubation.

3 INTRODUCTION

3.1 Anatomy and physiology aspects

Through nasal and oral cavities, the air enters into the airway and goes through the pharynx and larynx to the lungs. Is important to know this way to know where the endotracheal tube (ET) is when we are carrying out the intubation and to place it in the good way.

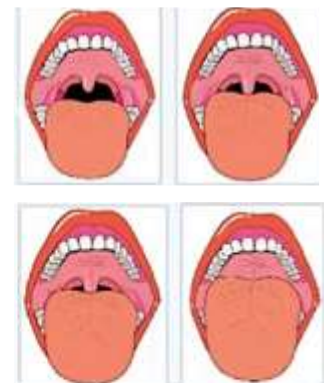
To perform a good intubation we have to know about airway anatomy. This system is composed by the nasal cavity, oral cavity, pharynx, larynx, trachea and principal and secondary bronchi. Moreover, there are many differences of size, shape and position between an older child or an adult and a NN, making the interventions and handling different. Is important to appreciate that the anatomy of a neonate (NN) is more difficult to identify the different parts of the airway and they are smaller than in an older child or an adult.(1)

The main anatomical differences of the airway found in a NN are: (2,3)

- The tongue is bigger in relation to the oral cavity. To evaluate this anatomy difference, we will use the Mallampati classification. (see Table 1) (4,5)
- The larynx is higher between C2-C3.
- The epiglottis presents different form being longer and thinner.
- The trachea is narrower, favoring the impact of the tube during EI and shorter, producing selective intubation (especially of the right bronchus) more frequently.

Table 1 Mallampati classification

CLASS	DESCRIPTION
Class 1	Visibility of the soft palate, uvula and tonsil pillars.
Class 2	Visibility of the soft palate and uvula.
Class 3	Visibility of the soft palate and the base of the uvula.
Class 4	Impossibility to see the soft palade.



The resistance of air passing through a tube is measured by the diameter and length of said tube. Therefore, as the neonatal respiratory system is narrower throughout his length, air resistance is increased making it more difficult to pass through and favoring that the airflow is more turbulent. Also, NN consume more oxygen and have a small reserve induce a quickly desaturation during apnea and is often followed by bradycardia.(3,6,7)

3.2 Evolution of the intubation

The initial management of NN has traditionally been based on early endotracheal intubation (EI) and the administration of prophylactic surfactant, thus reducing the mortality of preterm infants in recent years. Nowadays, CPAP is used for several respiratory disorders that occur in the neonate such as respiratory distress syndrome, apneas and even in the resuscitation of NN in the NICU and delivery room. (8)

With the increasing use of CPAP, we also need to add the use of surfactant in the NN and the prenatal treatment with corticosteroids as fundamental pillars in the lower use of EI in NN. The very positive experience of their use has concluded to consider these techniques as respiratory support in NN, especially in very premature infants in which EI was the only option. It is important to highlight that the fact of considering the use of CPAP or intubation is a clinical decision, where many factors must be evaluated such as pulmonary mechanics, neonatal weight, cardiovascular and neurological status, the presence or absence of infection and, more important, the degree of respiratory effort. A complete clinical evaluation with a good approach to these factors is fundamental. (9,10)

Then, due to the increasing use of non-invasive devices for respiratory diseases in NN such as BIPAP, CPAP, high-flow nasal cannulas, surfactant use, prenatal corticoids treatment... EI is a technique that has been displaced in his use for situations that are more complex and as a last resort.

3.3 Definition

The EI is the introduction of a tube into the trachea through the oral or nasal cavity with the aim ventilating, oxygenate, aspirate and protect the bronchial tree.(1)

We have two principal type of EI, direct or video-laryngoscope (VL). Usually we intubate through the nasal cavity when we use direct laryngoscope (DL) and through the oral cavity when is VL.

Until the 20th century, the intubations were carried out with the fingers, introducing the ET manually without having a vision of the airway. At the middle of the century, an apparatus capable of opening and allowing the view of the airway was invented. This device, the laryngoscope, was curved and later, with the introduction of the child's EI, Miller's straight blade appeared allowing the view of the difficult airway, as it is in the neonate. Nowadays, in addition to using the straight blade, it is carried out through the nasal cavity and the ET is introduced with tweezers when we realize that this way performing less physical trauma in the neonatal airway (10). EI with DL is done through nasal cavity because it supposed less trauma for the patient, less movement of the tube when it is placed and usually less adverse events.



Figure 1 Types of laryngoscope blades.

Video assisted techniques become an important tool in different parts of the clinical practice. As the others machines, VL is introduced as airway manager, becoming the standard procedure for patients with known or suspected difficult airways, with the potential for decrease morbidity and saving time to intubate. As we have explained before, these patient with difficult airway management usually are the NN, so VL is considered a good tool in NN EI. (11,12)

VL has a fiberoptic camera lens into the light source of a laryngoscope blade, expanding the viewing angle offered by the DL. The VL is connected to a video monitor, which displays a magnified image that helps the specialist to carry out the intubation. Video-assisted intubation offers teaching opportunities through better identification and recognition of anatomy, and the possibility for both teacher and trainer to share the same visual landmarks allowing guidance of the resident throughout the procedure.(13)



Figure 2 Video-laryngoscopy.



Figure 3 Images of the vocals cords done with a VL.

In both processes, the length of the tube will be assessed according to the WG of the patient and it can be seen in Annex 1. (14)

3.4 Incidence and process

We know that in 2016, in NICUs of the Josep Trueta hospital, 416 patients were admitted, of whom 43 were intubated, and then there is a 10.3% of patients intubated due to causes such as hypoxemia, apnea, shock, hypercapnia, neurological disorders and ET replacement.(15)

The following scheme shows the steps of an intubation (1), extended in annex 2.

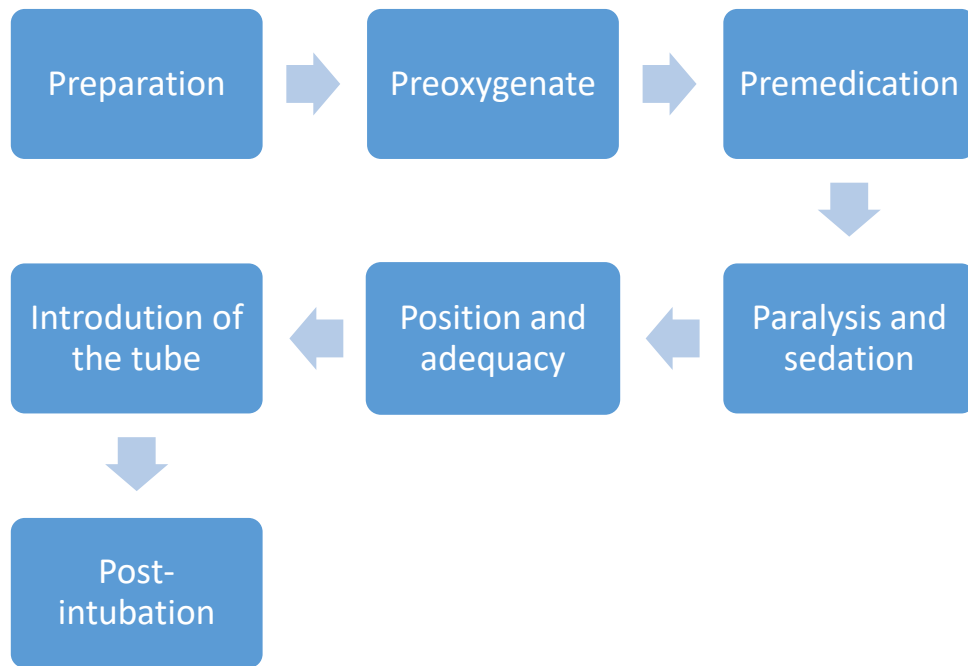


Figure 4 Steps in an EI.

3.5 Complication of neonatal intubation

EI is a very important skill that neonatologists have to know in his professional life and it carries some risks that the neonatologist has to take and deal them. In addition, the intubation has some complication that the professional has to manage to avoid them and get a success intubation.

These complications can be observed in table 2.

Table 2 Complication of intubation

Severe	Not severe
<ul style="list-style-type: none">• Severe bradycardia or loss tissue perfusion requiring chest compression for at least 1 min• Esophageal intubation with late recognition.• Bronchopulmonary aspiration.• Hypotension that requires volume loading and / or vasopressors.• Laryngospasm.• Pneumothorax / pneumomediastinum.• Direct airway injury.• Severe desaturation (more than 20% in relation to basal O2 sat).• Death.	<ul style="list-style-type: none">• Bronchial intubation.• Esophageal intubation with early recognition.• Vomit without aspiration.• Hypertension that need treatment.• Epistaxis.• Lip or oral trauma.• Dysrhythmia, including bradycardia that need chest compressions for less than 1 minute.• Pain or agitation that need treatment.

3.6 Factors of the intubation

There are some factors that intervene in the complications explained upside and Elisabeth E. Foglia et al. 2005 and T. Sawyer et al. 2016 divide them in some groups: according to the patient and practice, and according to the intubator characteristics and unit characteristics. (16,17)

Patient and practice: only ventilation failure demonstrate that is an intubation indication that has relation with adverse events. Physiologic stability and airway anatomy are some of the patient factor that we can found and medication and equipment about practice factors.

Intubator characteristics: the experience of the professional is the most important factors related with adverse events.

There also is some factors called system characteristic that it talks about the microsystem and safety culture of the NICU. It refers to the importance of building a system support to do the NN EI safer in NICU.

All these factors are related in Figure 5.

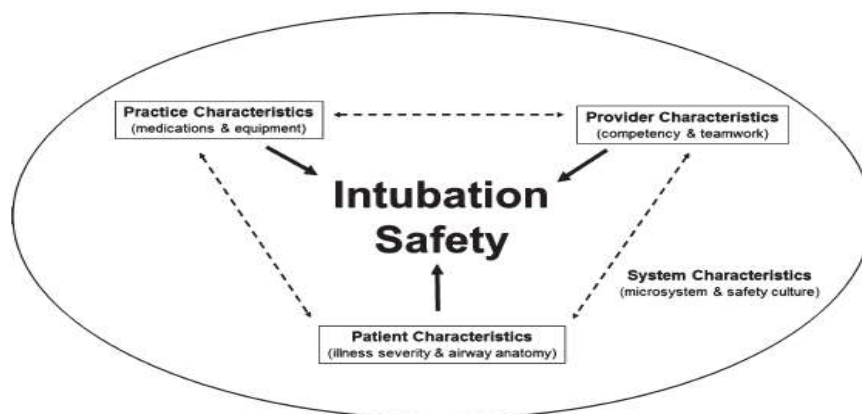


Figure 5. Factors associated with a safety and success intubation(17)

3.7 Intubation training

Neonatal EI is a difficult practical skill to manage, which it cannot be learnt from a textbook. The best way to acquire the ability to carry it out is to practice it in a controlled environment with senior supervision. Nevertheless, you have to reach some knowledge about it, and this part is the only theoretical learning. Studies show that to get a high success rate, you have to be trained to do so.(3,18,19)

For example, a study on the University of New Mexico that collect from a database of North America and Canadian (NEAR 2), they studied more than 6,000 EI attempts (7,498) performed by emergency physician and emergency resident. Their results are that in emergency physician they get a 90% of success rate attempts and in emergency resident was 83%. In addition, they separate the emergency resident for years of experienced and demonstrate that the first year was a 72% and the last year was an 82% of success rate on the first attempt. (20)

This training will be stipulated with the follow stages(17):

➤ **Theory learning**

This stage is the theoretical part of the anatomical knowledge and theoretical reading of EI.

➤ **Observation**

The process of watching a number of times (between 5 and 10 times) how the intubation is performed by a specialist.

➤ **Practice**

Use the knowledge learned to practice intubation by VL and by DL in mannequins, through a simulation course with an approximately duration of 6 hours.

➤ **Performing the procedure in real life**

The resident has to demonstrate the theoretical knowledge and skills learned and they will be tested in real situations. This final stage of the training is the one that will be considered as being part of this clinical trial. In other words, all residents to be included in the trial must have successfully passed all previous stages of the training process and make two EI successfully and are therefore ready to participate in the trial to complete the final stage of their training process.

In 2002, in the University of California, San Diego carried out a study about successful intubation in NN in NICU during 10 years performed by hospital staff (pediatric trainees, respiratory care practitioners, neonatal nurse practitioners, attending neonatologists, and anesthesiologists).

They did 5051 successful intubation with 9190 attempts, a 55% success rate. They also demonstrate that if you have a training about EI you will obtained more successful intubation (45% in pediatric resident, 65% in neonatologist).(21)

4 JUSTIFICATION

NN EI is an important skill that every neonatologist should master. Therefore, learning how to intubate correctly as a NN is needed. Sometime it's difficult to carry out this procedure and one has to be trained to do it.

Nowadays there is no any stipulated training to prepare new resident or less experienced neonatologists in EI. Therefore, with this study we wish to test an intubation training that aims to improve this skill in less experienced specialists taking advantage of the new technological advances to do so, because we know that there is higher success rates and decreased duration of successful attempts as the level of experience of the operators increased. Thus, it is important to add this training to the clinical practice of non-experienced neonatologists. (18)

Due to the increasing use of non-invasive devices for respiratory diseases in NN such as BIPAP, CPAP, high-flow nasal cannulas, among others, intubation is a technique that has become less commonly used, as it has been reserved as a last resort for more complicated clinical cases. (9,22) Therefore, the training in the intubation of any professional is of great importance. In addition, our study group (NN) increases the importance of the EI knowledge, as it is the most difficult patients to carry out due to his complex anatomy.(23)

Nonetheless, new devices have been introduced, such as VL, to facilitate intubation in those professionals with less experience in order to improve it and speed it up in those who have sufficient experience. With this study, we want to introduce, together with an intubation training, the use of the VL in the practice of a NICU in a safe way, checking that its use helps to improve the process of intubation in NN. Nowadays, technological tools help us to intubate, but we have to know how to use them.

This study is also relevant as there are many studies about intubation in adult and pediatric population, but in NN, there is no studies about this procedure. Taking this into account, we think that it is really important to know and implement a protocol of intubation in NN.

5 HYPOTESIS AND OBJECTIVES

- **Hypothesis**

A resident using VL has the same complication rate than a neonatologist using DL in a NN intubation.

- **Objective**

To analyze the complication rate using VL by a resident versus DL by a neonatologist in a NN intubation.

6 METHODS

6.1 Study design

A non-inferiority, prospective, multicenter, randomized, open-labelled, parallel-group trial that compares DL by a neonatologist versus VL by a resident during NN intubation.

6.2 Research population

In this study, we will include every preterm and term NN that need an intubation in NICU, with these indications:

- **Hypoxemia.** It is an abnormally low level of oxygen in the blood. In term NN, we will define as a partial arterial pressure oxygen value below 50 mmHg with an oxygen concentration upper 50%, but in preterm NN is acceptable partial arterial pressure oxygen values below 40 mmHg due to the high levels of fetal hemoglobin that the preterm infants have.
- **Shock.** Any type of shock that does not respond to the corresponding treatment, including inotropic and/or fluids.
- **Hypercapnia.** High CO₂ level in arterial blood (over 60 mmHg with pH <7,25)(24)
- **Apnea.** When the NN stops breathing for longer than 20 seconds and does not respond to the treatment, including caffeine or intermittent mandatory ventilation nasal.

- Neurological conditions. This indication refers to the fact that the patient cannot breathe by himself/herself because of an abnormality in the respiratory center.
- ET replacement. As in the case of air leak or accidental extubation.

Table 3. Inclusion and exclusion criteria of EI.

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> • Hypoxemia • Shock • Hypercapnia • Apnea • Neurological conditions • ET replacement 	<ul style="list-style-type: none"> • NN with congenital malformation of the airway. (See annex 3) • Emergent intubation: intubation must be carried out, precluding the possibility of randomization in the. • NN <30 weeks of gestation.

6.3 Sample size

The free online application Sealed Envelope Ltd. 2012 has been used to calculate the sample size.

Accepting an alpha risk of 0.05 and a beta risk of 0.20, with a non-inferiority limit (named gamma) of 0.05, and a complication rate of 18%, we need 731 patients in each group, being thus a total of 1462 patients. Thus, if there is truly no difference between one group and the other group in the complication rate after intubation, 1462 patients are required to be sure that the upper limit of one-sided 95% interval will excluded a difference (greater 5%) in favor of one group.

6.4 Time of recruitment

It's difficult to know exactly how many NN are intubated in the different NICU in Spain. However, with SoftNeo we can know how many NN are intubated in the NICU of the Hospital Universitari Josep Trueta, and then extrapolate it to the other hospitals.

	2010	2011	2012	2013	2014	2015	2016
Ventilación convencional	72	58	42	40	47	49	43

Table 4. Patients who needs intubation in the Hospital Josep Trueta NICU.

As we need 1462 patient to carry out this study, we have to design a multicenter study with the participation of hospitals with level IIIB NICUs (25) from Catalonia, Madrid, Andalusia, and Valencia. With the adequate collaboration and coordination, we can enroll the 1462 NN in 12 months (1 year).

The Hospitals that we will participate in the study are:

- Catalonia: Hospital Josep Trueta, Hospital Vall d'Hebron, H. Sant Joan de Deu, Hospital de la Santa Cruz y San Pablo, Hospital Parc Taulí, Hospital Joan XXIII, Hospital Can Ruti, Hospital Arnau Vilanova.
- Madrid: Hospital La Paz, Hospital 12 de Octubre y Hospital Gregorio Marañón.
- Andalusia: Hospital Virgen de la Macarena de Sevilla.
- Valencia: Hospital La Fe de Valencia.

6.5 Variables

6.5.1 Independent variable

- **Specialists experience and type of intubation**

This variable is the combination of the experience of the specialist, expressed in years of work in neonatology department (see below), and the type of intubation, video assisted or DL. Such the combination is a dichotomous categorical qualitative variable, which will be expressed in two groups, resident with VL and neonatologist with DL.

6.5.2 Dependent variable

- **Complication rate**

This variable will be measured as a dichotomous categorical qualitative variable (yes or no).

The complication rate is the existence of any of the below list adverse effects due to the process of intubation that concludes 10 minutes after the placement of the tube in the trachea. In addition, we have to specify if these complications are severe or not severe, even we will consider them as a rate of presence of complications.

These complications include:

Severe:

- Severe bradycardia (<60 bpm) or loss tissue perfusion requiring chest compression for at least 1 min.
- Esophageal intubation with late recognition, after checkup with stethoscope and ray-x.
- Bronchopulmonary aspiration, we can observe that the diffuse confluent densities are distributed in the apical segments in the chest ray-x.(26)
- Hypotension that requires more than 10 cm/kg of crystalloids loading and/or vasopressors drug or increasingly the previous doses.
- Laryngospasm, an uncontrolled/involuntary muscular contraction of the vocals folds. You can see it directly or through the images from the video.
- Pneumothorax / pneumomediastinum, that causes respiratory compromise and you check in the chest ray-x.
- Direct airway injury, check with the direct visualization of the injuries.
- Severe desaturation (more than 20% in relation to basal O2 sat).
- Death, during the intubation.

Not severe

- Bronchial intubation. Unilateral breath sound, as checks with a stethoscope.
- Esophageal intubation with early recognition by ray-x.
- Vomit without aspiration.
- Hypertension that needs vasodilator treatment.

- Epistaxis.
- Any degree of lip or oral trauma.
- Dysrhythmia, including bradycardia that needs chest compressions for less than 1 minute and/or drugs.
- Pain or agitation that need treatment.

6.5.3 Co-variables.

- **Gestational age**

It will be calculated from the best obstetric estimate based on early prenatal ultrasound and obstetric examination.

It is a continua quantitative variable (weeks of gestation).

We will categorize it the following groups of age: over 37 GW (>37 GW) and under 37 GW (<37 GW).

- **Mallampati score.**

It is an ordinal qualitative variable. The following categories will be considered(4,5):

- Class 1: Visibility of the soft palate, uvula and tonsil pillars.
- Class 2: Visibility of the soft palate and uvula.
- Class 3: Visibility of the soft palate and the base of the uvula.
- Class 4: Impossibility to see the soft palade.

- **Gender.**

It is a dichotomous nominal qualitative variable (Male and female).

- **Mortality.**

Defined as death during the intubation process. It is a dichotomous categorical qualitative and also together with the abovementioned complications, a safety variable.

As listed above, we will also consider the mortality as a complication that has to include in the variable 'complication rate'.

6.6 Study intervention

We have two type of intubation procedure that we want to study VL by a resident and DL by a neonatologist.

On one hand, you can difference resident and neonatologist with years of clinical practice.

The resident is whoever, after finishing the Medicine degree, is doing the pediatric specialty. It is a period of 4 years that include clinical practice in different departments of the specialty. For the purpose of this study, the resident must be in the third or fourth year of residence and must have had practice for a minimum of 6 months in the neonatology department.

The neonatologist is a specialist in neonatology, with a minimum of 5 years experience in the service.

On the other hand, the trial will consider two types of intubation:

VL has a fiberoptic camera lens into the light source of a laryngoscope blade, expanding the viewing angle offered by the DL. The VL is connected to a video monitor, which displays a magnified image that helps carry out the intubation. Video-assisted intubation offers teaching opportunities through better identification and recognition of anatomy, and the possibility for both teacher and trainer to share the same visual landmarks allowing guidance of the resident throughout the procedure.

In the case of DL, the laryngoscope is used to open the airway and see directly the opening of the larynx. It will be done through the nasal cavity and the right ET is introduced with tweezers into the airway.

6.6.1 Training

All the residents who will participate in this trial must receive a training to know how to use the VL and how to intubate a NN.

This training will consist in four stage: theory learning, observation, practice and performing the procedure in real life. (17)

➤ **Theory learning**

This stage is the theoretical part of the anatomical knowledge and theoretical reading of EI.

➤ **Observation**

The process of watching a number of times (between 5 and 10 times) how the intubation is performed by a specialist.

➤ **Practice**

Use the knowledge learned to practice intubation by VL and by DL in mannequins, through a simulation course with an approximately duration of 6 hours.

➤ **Performing the procedure in real life**

The resident has to demonstrate the theoretical knowledge and skills learned and they will be tested in real situations. This final stage of the training is the one that will be considered as being part of this clinical trial. In other words, all residents to be included in the trial must have successfully passed all previous stages of the training process and make two EI successfully and are therefore ready to participate in the trial to complete the final stage of their training process. As we are comparing experience, when the resident has performed seven EI, we will consider that he/she has enough experience and they will be removed from the study.

6.6.2 Randomization

Every NN that are in NICU and they need an intubation and meet the inclusion criteria to enter in this study has to be randomize.

The statistical specialist, has built a randomization sequence using a statistical software. This provides a simple random sampling. From each patient we will obtain who has to do the intubation, the resident or the neonatologist.

As this is an intervention, the doctor has to know what he/she is doing, so this study cannot be blinded.

Patients who need to be intubated in NICU will be randomized in order to be assigned to one of the two intubation procedures:

1. VL by a resident.
2. DL by a neonatologist.

The Case report form (CRF) (See annex 4) will be filled out by the investigators at each of the participating centers.

6.6.3 Masking techniques

Due to the inherent limitations of procedure strategies, there is no option to do a triple blinded study. The doctor will be aware of the EI procedure assigned to every case.

Therefore, the only possibility to reduce the bias of the study is to blind the person who will analyze the statistics.

6.6.4 Premedication

After randomization, we have to medicate the patient and we will use NEOFAX to know which drugs we have to administrate.

The drugs that every NN will receive are the commonly that it uses in the habitual clinical practice:

- Atropine. This drug is used to avoid the vagal reaction that all patients have when a tube is introduced through their airway. Usually we use 0.02 mg/kg of atropine intravenous.
- Fentanyl. This drug is an analgesic used to reduce the pain generated by intubation in the NN. Fentanyl with atropine are the two drugs commonly used today in neonatal intubation.
- Midazolam. This drug is used in patients above 34 WG (27). It is a sedative, so it will be used in patients in whom atropine and fentanyl are not sufficient for appropriate sedation prior to intubation.
- Rocuronium. It is a paralyzing drug, so it will be used when we cannot appropriately sedate the patient with the previous drug.

6.6.5 Intubation procedure

See annex 2.

6.6.6 Confirmation of tube location

Once done the intubation, you have to check the correct ventilation of the patient and we have some ways to check if the tube is placed well or not, by chest ray-x or by stethoscope.

We will do it by chest ray-x and we have to observe that the ET is between the vertebra T1 and T2. (28)

6.7 Data collection

The data will be prospectively collected using the CRF. With such CRF, we will keep all data of the EI that will be carried out in the different NICU.

We will register all the information about each EI in the CRF. This includes the WG, the NN weight, the place that we carry out the intubation, the context and the reasons that we do it, we have to register who does it, the principal disease of this patient, why the patient has a respiratory problem, which kind of intubation we carry out, which kind of laryngoscope we use, how we will check that the tube is in the correct place and we have a success intubation, which medication we manage and the list of complications that can appear during the process (see annex 4).

Every week each neonatologist manager from each hospital will collect the information and add them in "NEOAIR", a database that every professional that is participating in our study has a user and password to access. In this database, each one has to type the data of his patients every time that they have intubated one. Everyone will only have access to their patients, but they will be able to know how the study is developing, having a summary of the results in other hospitals. Instead, the study coordinator has the access of data of every patient who is included in the database and know the study is developing at any time.

7 STATISTICAL ANALYSIS

- Descriptive statistics:

We will carry out a descriptive analysis of all variables.

- ✓ Categorical variables will be described as percentage and
- ✓ Quantitative variables will be expressed by means \pm standard deviation (SD)

- Bivariate analysis

Proportions between qualitative variables (specialist experienced and complication rate) will be compared with Chi-Square test and Exact Fisher test when the expected frequencies are <5%.

- Multivariate analysis

The analysis of response to treatment for endpoint variable (complication rate) between independent treatment and control groups (main objective of the proposal) will be performed by a lineal regression analysis. Differences in changes across intervention groups will be tested by the interaction term among the intervention variable and the endpoint variables of the study. Models will be adjusted for potential confounders (age, gender, gestational age, Mallampati score). An intention-to-treat analysis and a per-protocol analysis will both be performed. Imputation of missing values for endpoints variables will be performed using the latest observed values for each variable and subject.

Similarly, a general linear model for repeated measures will be used to test whether specialist experienced and type of intubation, computing each of the complications rate as the dependent variable, and adjusting for similar confounding variables. A p value <0.05 will be considered statistically significant.

8 LIMITATION

- It is a clinical trial, so by definition the study has a higher cost. Especially with the population that we analyze. The infants have a higher insurance cost. Even so, it is the best design to answer our hypothesis.
- The study may be an important step to start implementing a training in different NICU to improve the skill of EI in professionals in this field. Even though we have some exclusion criteria that preclude the generalization of our results to all NN, it is expected that, by using this training process in the future, more residents will be capable to do an EI in a difficult airway.
- Being a multicenter study, it requires a major elaborate organization than if we do it only in one hospital. This implies that the study coordinator has to make sure that anyone who enters data in NEOAIR knows how to do it correctly.
- The different hospitals participating in the study should have previously worked together to avoid generating problems during the coordination and execution of the study and to facilitate communication between these centers.
- It is a clinical trial that will study the performance of two EI techniques and will be carried out in NN, so it cannot be double-blind. That is why it will be necessary that someone performs the statistical analysis without knowing which patient receives a technique and another receives another one, because the results of our study will come out of this analysis and they have to be without any bias.
- As we are comparing two experiences with an EI technique, when a resident, initially unexperienced, will perform more than seven EI, he/she will become in an experienced professional. Therefore, they will be removed from our study to avoid a researcher bias.

9 ETHICAL ASPECTS

This clinical trial follows the declaration of Helsinki involving ethical principles for Medical Research involving Human subjects (last actualization October 2013).

It must be approved by the Clinical Research Ethics Committee (CEIC) of all the centers participating in the study.

The research project will be performed according the Spanish laws related to clinical trials: “Ley 14/2007 de 3 de Julio, de investigación biomédica con procedimientos invasivos”

As this project involves NN, parents or legally authorized representatives have to sign two reports, one that every newborns that is accepted in NICU has to sign that authorize to perform any intervention in the kid (See annex 5) and the other one to participate in our study, after providing comprehensive information (See annex 6 and 7). All the data collected from each patient will be treated and used anonymously, preserving the confidentiality of the patient according to the “Reglamento (UE) 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”, and the “Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal”.

All the investigators will have to declare no conflict of interest.

10 WORK PLAN AND CHRONOGRAM

The study team will be composed by the study coordinator (SC), neonatologist expert (the neonatologist manager of each hospital) (NE) and resident (RS) from each hospital and the statistical specialist (SS).

The duration of our study will be two years and it will have four stages.

Stage 0. Protocol elaboration

- Activity 1. Elaboration of the protocol. (February-April 2019). During the first three months, SC will search the bibliography and elaborate and described the protocol.
- Activity 2. Meeting 1 (May 2019). It selects the hospital that will participate in the study, each one will select their neonatologist expert and resident, and they will discuss the protocol and CRF if everyone is agree with the procedure and want to be included into the study. All the meeting that we will have in our study will carry out in the Hospital Josep Trueta.
- Activity 3. Ethical evaluation (May 2019). Each hospital CEIC has to give the ethical approval of the protocol.

Stage 1. Training

During this stage, every RS of each hospital will receive the formation that consist in four stage: theory learning, observation, practice and try. (17) This stage will last 1 month (June 2019).

➤ **Theory learning**

This stage is the theoretical part of the anatomical knowledge and theoretical reading of EI.

➤ **Observation**

The process of watching a number of times (between 5 and 10 times) how the intubation is performed by a specialist.

➤ **Practice**

Use the knowledge learned to practice intubation by VL and by DL in mannequins, through a simulation course with an approximately duration of 6 hours.

➤ **Performing the procedure in real life**

The resident has to demonstrate the theoretical knowledge and skills learned and they will be tested in real situations. This final stage of the training is the one that will be considered as being part of this clinical trial. In other words, all residents to be included in the trial must have successfully passed all previous stages of the training process and are therefore ready to participate in the trial to complete the final stage of their training process. As we are comparing experience, when the resident has performed seven EI, we will consider that he/she has enough experience and they will be removed from the study.

Stage 2. Experiment

- **Activity 1. Pilot experiment (July-August 2019).** With the aim to detect problems, mistakes of the CFR and any organization failures.
- **Activity 2. Meeting 2 (August 2019).** This meeting is not mandatory if everything in the previous stage is right. If it is necessary, we will do it to improve all things that are wrong and need a solution.
- **Activity 3. Data collection (September 2019-August 2020).** It will include the recruitment of the patients, randomization in both groups and data collection. It will be for 1 year (It can be modified; the aim is to enroll 1462 patients) and we will do the following activities:
 - SC has to randomize every intubation in each hospital.
 - NE or RS will carry out the intubation
 - Nursing has to fill the CRF.

- Activity 4. Meeting 3. (6 months after initiate data collection). The aim is to evaluate how is going the study. To check the data collection quality, to solve if there is any problem. This meeting will also be to interpret and discuss the results and check if the number of patients is enough and determine the duration of our clinical trial.

Stage 3. Data analysis and interpretation of the results.

It will be done by the SS during the study doing different activities.

- Activity 1. Preparation randomization. Design the statistical software that every hospital will use to carry out the randomization sampling. Done before starting the data collection phase (August 2019)
- Activity 2. Assessed statistical analysis. The SS will do it in the 250, 500 and 1000 enrolled infants with the finality to stop the study if some of our independent variable show relevant results. It will be done in November 2019, March 2020 and July 2020.
- Activity 3. Finally statistical analysis. The SS will analyze the data from the 1462 patients. It will carry out during September and October 2020.
- Activity 4. Meeting 5. This meeting has the objective to interpret and discuss the results from the statistical analysis. Done in November 2020.

Stage 4. Publication and dissemination of the research results.

Write and edit the article where we will show the results of our clinical trial. We will publish it in December 2020 and present in the AEP and SENEo congress in 2021.

	Activities	MONTHS 2019												MONTHS 2020												MONTHS 2021		Intervenor
		F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F		
STAGE 0	Elaboration of the protocol	■	■	■																								SC
	Meeting 1				■																							SC, NE, RS.
	Ethical evaluation				■																							CEIC
STAGE 1	Theory learning				■	■																						RS
	Observation				■	■																						RS
	Practice				■	■																						RS
	Performing				■	■																						RS
STAGE 2	Pilot experiment					■	■																					NE, RS
	Meeting 2						■																					SC, NE, RS
	Data collection							■	■	■	■	■	■	■	■	■	■	■	■	■								SC, NE
	Meeting 3													■														SC, NE, RS, SS.
STAGE 3	Preparation randomization						■																					SS
	Assessed statistical analysis									■				■				■										SS
	Finally statistical analysis																			■	■							SS
	Meeting 5																					■						SC, NE, RS, SS.
STAGE 4	Publication																							■				SC, NE, RS.
	Dissemination																								■	■		SC.

11 FEASIBILITY

This clinical trial will carry out in several Spanish hospital with level IIIB NICU (25) from the autonomous communities with high number of births, in order to ensure the research population enough to prove statically significant outcomes in the estimated time of 1 year.

As we evaluate a routinely procedure, the hospitals will provide the entire infrastructure that we need in our study: personal salaries, all the materials that we need in an EI included the VL, computers to send the CRF.

We know that is difficult to enroll 1462 infants for our study, but the importance of the study and the impact of the results, justifies the efforts. The NN are a population more vulnerable and increasingly present in our society thankful to the new technological advances so it is fundamental to know how to manage this group of patients.

12 BUDGET

	Description	Total cost
<u>STAFF</u>		
<ul style="list-style-type: none"> • Statistical Specialist 	40€/h x 70h	2,800€
<ul style="list-style-type: none"> • Study Coordinator 	350€/year. For 2 years.	700€
<u>TRAINING</u>		
<ul style="list-style-type: none"> • Qualified staff 	20€/h, for 6 hours. 13 hospitals	2,340€
<u>MEETINGS</u>		
<ul style="list-style-type: none"> • Coordination meetings 	50€/per. 13 persons. 4 meetings.	2,600€
<ul style="list-style-type: none"> • Analyze meeting 	50€/per. 13 persons. 1 meeting.	650€
<u>PUBLICATION and DISSEMINATION</u>		
<ul style="list-style-type: none"> • Cost of publication 		2,500€
<ul style="list-style-type: none"> • National journey to disseminate results 		1,000€
<ul style="list-style-type: none"> • International journey to disseminate results. 		2,000€
	<u>Total cost</u>	14,590€

13 PROJECT IMPACT ON THE NATIONAL HEALTH SERVICE

If our study will carry out and the results will be relevant and positive, the improvement that would be achieved will imply an important change in the clinical practice of this skill between the less experienced professionals.

A recent study at the Children´s Hospital of Philadelphia from the NEAR4NEOS(17) considers that the learning and training of difficult airway management should take an importance paper in the resident´s formation to improve the knowledge and the clinical assistance in the Spanish NICUs.

This study will also use to know what is the current situation of knowledge about the EI in Spain, since it will be carried out in various hospitals, offering us data that will help us to implement and/or reinforce the training in those centers where there is a high complication rate and make an improvement in neonatal EI.

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15 ANNEX

15.1 Annex 1 – Length and blade type of the endotracheal tube.(14)

Tabla 2.

Edad	Guedel	Bolsa autoinflable	Tubo ET	Pala laringoscopio
Prematuro	00	250 ml	2,5-3	Recta n.º 0
RN	0	250 ml	3	Recta n.º 0
RN-6 m	0	500 ml	3-3,5	Recta n.º 0
6 m-1 a	1	500 ml	3,5-4	Recta o curva n.º 1
1-2 a	2	500 ml	4-4,5	Curva n.º 1-2
3-4 a	3	500 ml	4,5-5	Curva n.º 2
5-6 a	4	500 ml-1,5 litros	5-5,5	Curva n.º 2
7-8 a	4	1,5 litros	5,5-6	Curva n.º 2-3
9-10 a	4,5-5	1,5 litros	6-6,5	Curva n.º 2-3
11-12 a	4,5-5	1,5 litros	6,5-7	Curva n.º 2-3
13-14 a	4,5-5	1,5 litros	7-7,5	Curva n.º 2-3

15.2 Annex 2 – Procedure of an endotracheal intubation. (29)

Tabla 67-4 Intubación de secuencia rápida		
PASO	PROCEDIMIENTO	COMENTARIOS/EXPLICACIONES
1	Obtener una anamnesis breve y realizar la valoración	Descartar alergias farmacológicas; examinar la anatomía de la vía respiratoria (p. ej., micrognatia, paladar hendido)
2	Preparar el equipo, la medicación, etc.	Ver las listas más adelante
3	Preoxigenar al paciente	Con bolsa/mascarilla, cánula nasal, carpa o con flujo directo
4	Premedicar al paciente con lidocaína, atropina	La lidocaína minimiza la elevación de la PIC con la intubación y puede aplicarse por vía tópica sobre las mucosas de la vía respiratoria como anestésico local La atropina amortigua la bradicardia asociada a la manipulación de las vías respiratorias altas y disminuye las secreciones de las vías respiratorias
5	Inducir la sedación y la analgesia	Sedantes: <i>Tiopental</i> (2-5 mg/kg): comienzo muy rápido; puede provocar hipotensión <i>Diazepam</i> (0,1 mg/kg): comienzo de acción en 2-5 minutos; eliminación en 30-60 minutos o más <i>Ketamina</i> (2 mg/kg): comienzo de acción en 1-2 minutos; eliminación en 30-40 minutos. Puede provocar alucinaciones si no se administran otros fármacos; aumenta la PIC, las secreciones mucosas, las constantes vitales y produce broncodilatación Analgésicos: <i>Fentanilo</i> (3-10 µg/kg, puede repetirse 3-4 veces): la administración rápida aumenta el riesgo de «rigidez torácica», dificultando la ventilación. Los efectos desaparecen en 20-30 minutos <i>Morfina</i> (dosis de 0,05-0,1 mg/kg): su efecto puede durar 30-60 minutos; puede dar lugar a hipotensión en los pacientes hipovolémicos
6	Tratamiento previo con relajantes musculares no despolarizantes	Dosis pequeña de relajante muscular no despolarizante (v. más adelante), con la intención de disminuir el efecto despolarizante de la succinilcolina, que se administra a continuación
7	Administrar relajantes musculares	La dosis de succinilcolina es de 1-2 mg/kg; provoca inicialmente contracción muscular y a continuación relajación. Sin embargo, esta despolarización puede elevar la PIC y la presión arterial. Comienzo de la relajación en 30-40 segundos; duración de 5-10 minutos Cada vez se utiliza más el tratamiento previo con un relajante no despolarizante, y en especial con rocuronio (1 mg/kg), cuyo inicio de acción es muy rápido y su duración breve. Otros relajantes no despolarizantes son vecuronio y pancuronio, ambos a una dosis de 0,1 mg/kg
8	Realizar la maniobra de Sellick	Presión sobre el cartilago cricoides para obstruir el esófago y evitar la regurgitación o la aspiración
9	Realizar la intubación endotraqueal	TE: seleccionar el tamaño apropiado para la edad y el peso del niño Palas del laringoscopio: existen numerosas palas de Miller y de Macintosh Paciente en decúbito supino; el cuello se extiende moderadamente hasta la posición de «olfateo»
10	Fijar el tubo y verificar su posición con una radiografía	TE fijado con esparadrapo a las mejillas y al labio superior o mediante un parche adhesivo a la piel cercana a la boca
11	Comenzar la ventilación mecánica	Verificar la colocación del tubo antes de ventilar con presión positiva; puede provocarse un barotrauma si el TE se introduce en uno de los bronquios

15.3 Annex 3 – Newborn malformation syndrome(7)

Table 1: List of possible factors complicating airway management in a number of congenital syndromes

Syndrome	Airway implication
Pierre robin sequence	Micrognathia, glossoptosis, cleft palate
Goldenhar syndrome	Micrognathia (unilateral), cervical dysfunction
Treacher Collins syndrome	Micrognathia, small oral opening, zygomatic hypoplasia
Apert syndrome	Limited cervical motion, macroglossia, micrognathia, midface hypoplasia
Hunter and Hurler syndromes	Cervical dysfunction, macroglossia
Beckwith-Wiedemann syndrome	Macroglossia
Freeman-Sheldon syndrome	Circumoral fibrosis, microstomia, limit cervical motion
Down syndrome	Atlantooccipital abnormalities, small oral cavity, macroglossia
Klippel-Feil syndrome	Cervical fusion
Hallermann-Streiff syndrome	Microstomia
Arthrogyposis	Cervical dysfunction
Cri-du-chat syndrome	Micrognathia, laryngomalacia
Edwards syndrome	Micrognathia
Fibrodysplasia ossificans progressiva	Limited cervical motion

15.4 Annex 4 – Case Report Form

ETIQUETA IDENTIFICATIVA

SETMANES DE GESTACIÓ

EDAT (dies) (<24 hores, dir hores)

PES (Grams)

LLOC

Paritori

UCI-N

SITUACIÓ

Emergent

Urgent

Electiva

INDICACIÓ

Hipoxèmia

Hipercàpnia

Xoc

Apnees

Neurològic

Urgència PCR

Recanvi TET

VERIFICACIÓ PRÈVIA A L'INTUBACIÓ

Núm. Metges

Núm. Infermeres

Líder

Oxigen i bossa

autoinflable

Aspiració

Tub

Medició contínua de: Escriure valor de TA:

FC

FR

TA

Capnografia

MALALTIA DE BASE

Quina?

HISTÒRIA PRÈVIA DIFICULTAT EN VIA AÈRIA

Quina?

ÚS DE GUIA

INTUBACIÓ

Nasal

Boca

PALA

Corba

Recte

UTILITZACIÓ DE

Videolaringoscòpia

Capnografia

COMPROVACIÓ AMB

Ecografia

Rx de tòrax

TA AL FINAL DEL PROCEDIMENT

PREOXIGENACIÓ

Sí

No

SEDACIÓ

Sí

Fàrmac:

No

Dosi:

ANALGÈSIA

Sí

Fàrmac

No

Dosi:

PARALITZANT

Sí

Fàrmac

No

Dosi

ATROPINA

Sí

No

Dosi:

PERSONA QUE INTUBA

Resident

Senior (>5a d'exp)

PERSONA QUE ASSISTEIX

Resident

Senior

NÚMERO D'INTENTS

FIXACIÓ

Clàssica

Dispositiu

SONDA DESPRÉS DE LA INTUBACIÓ?

No

Nasogàstrica

Sí

Orogàstrica

COMPLICACIONS

GREUS

Bradicàrdia severa o pèrdua de perfusió tissular que requereix compressió toràcica menys de 1 minut.

Intubació esofàgica amb reconeixement tardà.

Broncoaspiració per vòmit.

Hipotensió que requereix càrrega de volum +/- vassopresors.

Laringoespasma.

Pneumotòrax/pneumomediastí.

Lesió directa de la VA.

Desaturació greu (>20% en relació a la SatO2 basal).

NO GREUS

Intubació bronquial.

Intubació esofàgica amb reconeixement immediat.

Vòmit sense broncoaspiració.

HTA que requereix tractament.

-
- Epistaxis.
 - Trauma labial o oral.
 - Disrítmia (incloent Bradicàrdia que requereix compressió toràcica menys de 1 minut).
 - Dolor o agitació que requereixi tractament.
-

15.5 Annex 5 – Informed consent to access into NICU



Dades del/la pacient
Cognoms:
Nom:
NHC:

Consentiment informat

Nom del procediment:

Procediments derivats de l'Ingrés al Servei de Cures Intensives Neonatals i Pediàtriques.

Descripció del procediment:

El seu fill/a ingressa en la Unitat de Cures intensives Neonatals i Pediàtriques perquè pateix una malaltia greu, que posa en perill la seva vida, i necessita un tractament i/o vigilància especial.

Riscos generals:

Poden ser necessàries mesures o tècniques que denominem de "suport vital", que no estan lliures de riscos que vostè ha de conèixer. En el cas concret del seu fill/a li explicarem quines d'aquestes actuacions seran utilitzades i per quin motiu, sempre que la urgència ho permeti.

Riscos específics:

Aquest riscos són variables en freqüència i gravetat depenent de la tècnica i del propi pacient, però els més freqüents són:

- Els derivats de la col·locació de catèters en venes i artèries que poden donar lloc a complicacions com hemorràgies, coàguls o infecció.
 - Intubació i ús de respiradors, utilitzats per ajudar a substituir la pròpia respiració, també poden tenir efectes no desitjats com infeccions pulmonars, fugida d'aire per trencament del pulmó, obturacions o lesions de la tràquea.
 - Reaccions adverses, fonamentalment a medicaments, per reacció al·lèrgica o efectes secundaris.
 - Toracocentesis: punció de l'espai pleural per fins diagnòstics i extracció d'aire o líquid amb fins terapèutics. Pot tenir efectes no desitjats com fugida d'aire per punció del pulmó, fugida d'aire sota la pell, hemorràgia pulmonar, lesió de vasos intercostals o lesió de les vísceres abdominals.
 - Pericardiocentesis: tractament del tamponament cardíac i anàlisi del líquid extret per fins diagnòstics. Pot tenir efectes no desitjats com lesió del miocardi, punció d'una artèria coronària, aritmies, lesió del pulmó o lesió de vísceres abdominals.
- Les persones que cuiden al seu fill/a coneixen aquestes possibilitats i estan atents a la seva possible aparició per combatre-les, cosa que generalment transcorre amb èxit. Tot i que els efectes secundaris poden agreujar la situació del pacient, els possibles beneficis d'aquestes mesures o tècniques superen àmpliament els riscos que comporten, és per aquest motiu que només es solen utilitzar en pacients greus.

Riscos personals:

-
-
-

.....pare/mare/tutor de.....
expressa que ha estat informat pel Dr/a..... del motiu pel que el meu fill/a ingressa a la Unitat de Cures intensives Neonatals i Pediàtriques, de les tècniques que poden ser necessàries aplicar-li i dels riscos que poden derivar-se de les mateixes. Comprenc el contingut d'aquest document, he rebut la informació suplementària sol·licitada i accepto les mesures necessàries. En qualsevol moment de l'evolució de la malaltia del meu fill/a podré reconsiderar aquesta decisió.

A Girona, a de de 20.....

Signatura i DNI de/la pacient o responsable legal.

Signatura del metge que informa i número de col·legiat

15.6 Annex 6 - Information sheet to parents / legal representatives

HOJA DE INFORMACIÓN AL PACIENTE

TÍTULO DEL ENSAYO CLÍNICO

Comparación entre dos procedimientos de intubación en neonatos: residente asistido por video-laringoscopia y neonatólogo por laringoscopia directa.

INTRODUCCIÓN

Nos dirigimos a usted para informarle sobre un estudio de investigación en el que se le invita a participar. El estudio ha sido aprobado por el Comité Ético de Investigación Clínica del Hospital Universitari de Girona Dr. Josep Trueta, de acuerdo a la legislación vigente, Ley 14/2007 de 3 de julio, de investigación biomédica con procedimientos invasivos.

Nuestra intención es tan solo que usted reciba la información correcta y suficiente para que pueda evaluar y juzgar si quiere o no participar en este estudio. Para ello lea esta hoja informativa con atención y nosotros le aclararemos las dudas que le puedan surgir después de la explicación. Además, puede consultar con las personas que considere oportuno.

PARTICIPACIÓN VOLUNTARIA

Debe saber que su participación en este estudio es voluntaria y que puede decidir no participar o cambiar su decisión y retirar el consentimiento en cualquier momento, sin que ello altere la relación con su médico ni se produzca perjuicio alguno en su tratamiento.

DESCRIPCIÓN DEL ESTUDIO

La intubación es un proceso ampliamente utilizado en la UCI Neonatal con el objetivo de mantener permeable la vía respiratoria de nuestros pacientes. Sin embargo, últimamente ha sido desplazada y cada vez se llevan a cabo un menor número de intubaciones. Por este mismo motivo, se está convirtiendo en una técnica realizada por un menor número de especialistas reduciendo aprendizaje por las nuevas generaciones. También se están añadiendo nuevas tecnologías, como en el resto de intervenciones, mejorando sustancialmente la efectividad del procedimiento. El objetivo de nuestro estudio es establecer un plan de entrenamiento y aprendizaje para aquellos especialistas con menos experiencia en este procedimiento y conocer si las nuevas tecnologías ayudan a dicha persona menos experimentada recogiendo la tasa de complicaciones que presentan cada especialista con una técnica u otra. Para ello se ha diseñado este ensayo clínico donde se realizará de forma aleatoria la intubación por video-laringoscopia por el residente o laringoscopia directa por el neonatólogo. Al ser un proceso aleatorizado todos los pacientes tienen las mismas posibilidades de ser intubado por un residente o un adjunto.

PROCEDIMIENTOS DEL ENSAYO

La intubación se llevará a cabo solo en aquellos casos en los que el paciente lo necesite y será realizado por el residente con video-laringoscopia o el neonatólogo con la laringoscopia directa.

BENEFICIOS Y RIESGOS DERIVADOS DE SU PARTICIPACIÓN EN EL ESTUDIO

Este estudio pretende ser una referencia, para establecer un entrenamiento y aprendizaje sobre la intubación en especialistas menos experimentados sobre el procedimiento.

Se realizarán análisis evaluadores internos durante el transcurso del estudio, para asegurar que no hay diferencias clínicamente relevantes entre los dos grupos de estudio.

La intubación presenta una serie de complicaciones asociadas como cualquier procedimiento invasivo explicadas en la hoja de acceso a la UCI Neonatal que usted ha tenido que firmar. Entre esas complicaciones podemos encontrar: bradicardia, intubación esofageal, aspiración broncopulmonar, laringoespamo, desaturación severa, muerte, entre otros.

COMPENSACIÓN ECONÓMICA

Su participación en el estudio no le supondrá ningún gasto. Usted no tendrá que pagar por la intubación ni recibirá una compensación económica

CONFIDENCIALIDAD

El tratamiento, la comunicación y la cesión de los datos de carácter personal de todos los sujetos participantes se ajustará a lo dispuesto en la Ley Orgánica 15/1999, de 13 de diciembre de protección de datos de carácter personal. De acuerdo a lo que establece la legislación mencionada, usted o su hijo podrán ejercer los derechos de acceso, modificación, oposición y cancelación de datos, para lo cual deberán dirigirse a su médico del estudio. Los datos recogidos para el estudio estarán identificados mediante un código y solo su médico del estudio/colaboradores podrá relacionar dichos datos con su hijo y con su historia clínica.

Sólo se transmitirán a terceros y a otros países los datos recogidos para el estudio que en ningún caso contendrán información que le pueda identificar directamente, como nombre y apellidos, dirección, nº de la seguridad social, etc. En el caso de que se produzca esta cesión, será para los mismos fines del estudio descrito y garantizando la confidencialidad como mínimo con el nivel de protección de la legislación vigente en nuestro país. El acceso a su información personal quedará restringido al médico del estudio/colaboradores, autoridades sanitarias (Agencia Española del Medicamento y Productos Sanitarios), al Comité Ético de Investigación Clínica y personal autorizado por el promotor, cuando lo precisen para comprobar los datos y procedimientos del estudio, pero siempre manteniendo la confidencialidad de los mismos de acuerdo a la legislación vigente.

Si usted decide retirar el consentimiento para participar en este estudio, ningún dato nuevo será añadido a la base de datos y puede exigir la destrucción de todas las muestras identificables previamente retenidas para evitar la realización de nuevos análisis.

15.7 Annex 7 - Informed consent to be added in the study

CONSENTIMIENTO INFORMADO DEL FAMILIAR RESPONSABLE O REPRESENTANTE

LEGAL

Yo (nombre y apellidos) en calidad de
(relación con el participante) de (nombre y apellidos del
participante)

He leído la hoja de información que se me ha entregado.

He podido hacer preguntas sobre el estudio.

He recibido suficiente información sobre el estudio.

He hablado con:

.....

(nombre del investigador)

Comprendo que la participación del paciente es voluntaria.

Comprendo que puede retirarse del estudio:

1º Cuando quiera

2º Sin tener que dar explicaciones.

3º Sin que esto repercuta en sus cuidados médicos.

Presto mi conformidad para que(nombre del participante)
participe en este estudio y doy mi consentimiento para el acceso y utilización de los
datos en las condiciones detalladas en la hoja de información.

Firma familiar o testigo:

Nombre:

Fecha:

Firma del investigador:

Nombre:

Fecha:

CONSENTIMIENTO INFORMADO ANTE TESTIGO

Yo (nombre y apellidos del testigo) declaro bajo mi responsabilidad que(nombre y apellidos del participante) ha leído (o se le ha leído, en caso de que no pueda leer, la hoja de consentimiento que se le ha entregado)

Ha leído la hoja de información que se me ha entregado.

Ha podido hacer preguntas sobre el estudio.

Ha recibido suficiente información sobre el estudio.

Ha hablado con:

.....

(nombre del investigador)

Comprendo que la participación del paciente es voluntaria.

Comprendo que puede retirarse del estudio:

1º Cuando quiera

2º Sin tener que dar explicaciones.

3º Sin que esto repercuta en sus cuidados médicos.

Presta su conformidad para participar en este estudio y da su consentimiento para el acceso y utilización de los datos en las condiciones detalladas en la hoja de información.

Firma testigo:

Firma del investigador:

Nombre:

Nombre:

Fecha:

Fecha:

