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ProActive Health

TIME TO PERFORMANCE LOSS ON ENDURANCE ELITE PREGNANT WOMEN: CHANGES IN $VO2_{MAX}$ AND MUSCULAR STRENGTH

A cohort study

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Bizitza honetan izan naiz samurai

Borroka etengabea eduki dut nonnahi

Etapa amaitu dela ohartzeaz ni gai,

Ez gaitezen geratu esperantzaren zai

Bizikleta izan da bizitzan aingeru,

Deabruak sahiesten, infernu ta zeru

Esan genezake "mendekurik ez du"

Izan gaitezen hurrengoen eredu.

Senda dezagun egindako mina,

Horretarako baitut mediku arima

Bideak izan ditu zailtasun adiña,

Buka dezagun, egindakoa egiña

Mila esker Aita, Ama, Urko eta Tasio,

Familia, gurekin ez daudenei eta familia sentitzen zareten guztioi

Axular Lizeoa, UVIC, UdG

I would like to show all my gratitude for guiding me during this project to Dr. Castillo Isern

ABBREVIATIONS

ACOG	American College of Obstetricians and Gynecologists
ACTH	Adrenocorticotropic hormone
BMI	Body Mass Index
CEIC	Comité d'ética d'investigació clínica
CRH	Corticotrophin-releasing hormone
EDC	Estimated Date of Conception
FEV1	Forced Expiratory Volume in 1 sec
HR	Heart Rate
hCG	Human Chorionic Gonadotropin
IOC	International Olympic Committee
LDL	Low Density Lipoprotein
PARMed-X	Physical Activity Readiness Medical Examination
PCOS	Polycystic Ovary Syndrome
PEFR	Peak Expiratory Flow Rate
RAAS	Renin-Angiotensin-Aldosterone System
RECap	Research Electronic Data Capture
SPSS	Statistical Package for Social Sciences
T3	Triiodothyronine
T4	Thyroxine
TBG	Thyroxin Binding Globulin
TSH	Thyroid Stimulating Hormone
VO2max	Volumen máximo de oxígeno
WADA	World Anti-doping Agency
WHO	World Health Organization

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ABSTRACT

BACKGROUND: Participation of women in elite sports has significantly increased, raising important considerations regarding pregnancy and sport performance. While moderate physical activity is generally safe, guidelines do not have specific recommendations for pregnant athletes, due to lack of evidence. Furthermore, optimal age for fertility coincides with peak performance, complicating even more reproductive planning. Combining social view for motherhood and their sports career, athletes need to take important decisions about their pregnancy without science-based information. There is no data to create an appropriate timeline for leaving competition, ensuring both maternal security and fetal well-being while acknowledging when performance levels decline.

OBJECTIVES: The main objective of the study is to analyse how pregnancy affects sport performance by determining the time when 10% of performance loss.

DESIGN AND SETTING: the study is designed as a multicentre international observational prospective cohort study.

PARTICIPANTS: Pregnant elite athletes practicing endurance sports.

METHODS: Ninety-seven subjects will be recruited during three years with a consecutive sampling method. Participants will be followed from pre-pregnancy period, following up to the third trimester of pregnancy, in order to determine the time where VO_{2max} and/or muscle strength drop 10%.

KEYWORDS: Pregnancy, Sports performance, Elite, Endurance, Time to Performance Loss, VO_{2max}, Strength

INTRODUCTION

PREGNANCY

The gestation is the physiological process where the fetus develops intrauterus. From fecundation to delivery, it lasts around 40 weeks and involves important physiological adaptations on pregnant women (1). With appearing social and economic factors, low pregnancy rate is an increasing problem (2).

Birthrate has turned in to a challenge nowadays, globally the population is increasing, but birthrate is reducing in developed countries (2). In Spain, last decades had declining trend, reaching an average of 1.12 children per woman in 2023 (3). Maroto-Navarro et al. concluded that women should not give up their professional aspirations to be mothers, but that a social impulse is needed to facilitate reproduction (2).

Pregnancy is a complex process; in order to carry out, maternal organism needs to develop physiological adaptations and adjust to the fetal demands. Most of the changes that occur during pregnancy, are gradually reversible in the puerperium (4,5).

In addition to physiological adaptations, hormones, especially sex hormones, play a major role in the development of pregnancy. The maternal endocrine system together with the placenta, create an appropriate environment for the fetus and its growth and subsequent delivery and birth (4).

PHYSIOLOGICAL CHANGES IN PREGNANCY

CARDIOCIRCULATORY CHANGES

The increase of blood-volume is the main change, it begins around 6th week of gestation, and it can go up to 2 litters gain. This growth is not homogeneous, the plasmatic volume increases more than globular one, consequently a relative anaemia is produced (4,5). This haemodilution is due to activation of Renin-Angiotensin-Aldosterone system (RAAS) and increased renal sodium reabsorption, resulting in extra water (5).

Heart rate (HR) is difficult and tricky to measure in pregnant women. It changes with position, but there is evidence of an additional 15-20 bpm at rest (4).

Literature describes cardiac output increases progressively (4–6). By the effect of peripheral vasodilatation, 40-50% of the cardiac output is gained for the 20th week (6). During the 3rd trimester, the uterus can compress inferior vena cava, resulting on a decreased cardiac output (4–6). Blood-flow redistribution to the uterus and placenta, leads to 25% of the cardiac output (5).

On the other hand, medium arterial pressure falls until 20th week, and reverses to achieve non-pregnant values in third trimester. Progesterone and relaxin levels elevate, relaxing smooth muscle and dropping like this peripheral vascular resistances (5,6).

Clinically, the appearing of oedema in inferior extremities is frequent (5). In addition, myocardial hypertrophy in left-ventricle, apex displacement and third Korotkoff sound (s3) may appear (4,5).

HAEMATOLOGICAL CHANGES

Haemodilution mentioned above, takes great importance for several hematologic parameters (4). Soma-Pillay et al. mention that this gain of volume may well be proportional to the birth weight (6).

The haematocrit and haemoglobin levels decrease due to the dilutional anaemia. Leucocytes are physiologically increased (>6000/mm^3) and platelets are deficient. Nevertheless, pregnancy is considered as an hypercoagulable state because of the risk of bleeding during partum, and some coagulation factors are boosted (4–6).

Regarding iron requirements, menstruation factor disappears, so the needs decrease in the first trimester (5). Subsequently, fetal demanding enlarges, for which iron and folate supplementation gets necessary (6,7).

RESPIRATORY SYSTEM'S CHANGES

The growth of uterus makes diaphragm to ascend reducing total lung capacity, but torax expansion allows vital capacity to maintain. Tidal volume per minute increases by 40-50% (4). Progesterone stimulates the respiratory centre, making organism to hyperventilate. This reduces pCO2 levels in blood and buffering effect of bicarbonate, stabilising mild respiratory alkalosis (4–6,8).

During pregnancy, dyspnoea without hypoxia is considered physiological (4,6). Maternal and fetal organs have more oxygen requirements (4–6,8). Nonetheless, Peak expiratory flow rate (PEFR) and forced expiratory volume in one second (FEV1) maintain their levels in the spirometry (6,8).

URINARY SYSTEM'S CHANGES

The RAAS activation cited above, enhances sodium absorption and consequently volume expansion. The decrease in peripheral resistances, produce physiological hydronephrosis in 80% of pregnant women (5).

There is an increase of glomerular filtration rate (50%) and renal plasma flow, so that creatinine, urea and uric acid clearance also increases (4,6,8). Besides, there is an increment on glucose, amino acid, protein and water-soluble vitamin excretion (4,5).

The fall of bicarbonate due to the respiratory alkalosis, does pregnant women lose buffering effect, making them more sensitive to grave ketoacidosis (4).

DIGESTIVE SYSTEM'S CHANGES

The uterus volume, moves and makes pressure on organs in the abdomen (4,5). Smooth muscle relaxation due to progesterone levels affects the tone of the sphincters, gall bladder and intestines. This makes 30-50% of pregnant women to have gastrointestinal reflux (4,8). Other common symptoms during pregnancy are anorexia, nausea and vomits. The Human chorionic gonadotropin (hCG), oestrogens and progesterone may cause these symptoms in the first few months (5).

METABOLIC AND ENDOCRINE CHANGES

Pregnancy is considered an anabolic state during the first week, with the aim of storing nutrients to complete fetal demands and afterwards lactation (5). As the weeks progress, maternal organism increments its insulin resistance, which makes glucose more accessible for being main energy source for the fetus (4,5). At the same time, the pregnant augments fat acid and lipid levels in blood, to facilitate their usage (9). During fasting, evidence describes an accelerated inanition to stimulate hunger (4).

In the liver, the augmentation of thyroxin binding globulin (TBG) production, causes T3 and T4 to increase (5,6). The hCG because of its appearance to thyroid stimulating hormone (TSH), makes TSH to decrease during the first weeks of pregnancy and it increases to superior limit for the third trimester (6). Iodine supplementation it's important during pregnancy, because iodine is actively transported through the placenta (5–7).

Prolactin hormone is elevated during the whole pregnancy, to prepare lactation (4).

Regarding adrenal hormones, RAAS activation increases aldosterone, which retains sodium and water, producing hypervolemia. This makes maternal organism to gain weight, it can reach 10kg before delivery (4,6). The placenta produces adrenocorticotropic hormone (ACTH) and corticotrophin-releasing hormone (CRH), what creates physiologic hypercortisolism, making glucose tolerance difficult (5,10).

Fetal skeletal development requires lot of calcium, this demands make calcium levels to decrease, causing relative osteoporosis during pregnancy and lactation (4).

IMMUNOLOGICAL CHANGES

There is an immunological tolerance mechanism to prevent embryo rejection. Local inflammation in the endometrium allows the implantation and placenta formation (5,11). In general, immune adaptative response is reduce, while innate immunity augments (12).

CHANGES ON GENITALIA

The increment of oestrogens and vascularity, produces hyperaemia in genitalia. Vaginal and cervix secretion augments, changing to more acid pH to protect from infections. The uterus, increases muscles fibres and contractile capacities, to make contractions during delivery (4). To facilitate labour, the sacroiliac joint gets loosened, and the mobility of pubic symphysis is increased. The spine changes to lordosis position in the lower back (6).

HORMONES IN PREGNANCY

Hormonal changes during pregnancy are so important, that a new endocrine structure is created, the placenta. It secrets various hormones including prolactin, sex hormones and neuroactive hormones, which affect and adapt systems in the maternal organism (13).

The placenta is the vital structure of communication between maternal and fetal blood, allowing them to interact with gas and nutrient transport. Apart from endocrine activity, it also has his role in immunity through hormonal changes. Creating a favourable environment for fetal development and getting ready for delivery (14).

Studies have been done on how hormones affect exercise capacity during menstrual cycle, but evidence is lacking for pregnancy. The last meta-analysis about menstrual cycle showed that studies had small significance of hormone effects on general population, but that this small variation could be differential for elite-athletes, where marginal gains become important (15).

Considering, hormonal levels multiply their levels during pregnancy, this effect could be increased. Therefore, analysing sexual hormones during pregnancy could be of great importance regarding exercise performance.

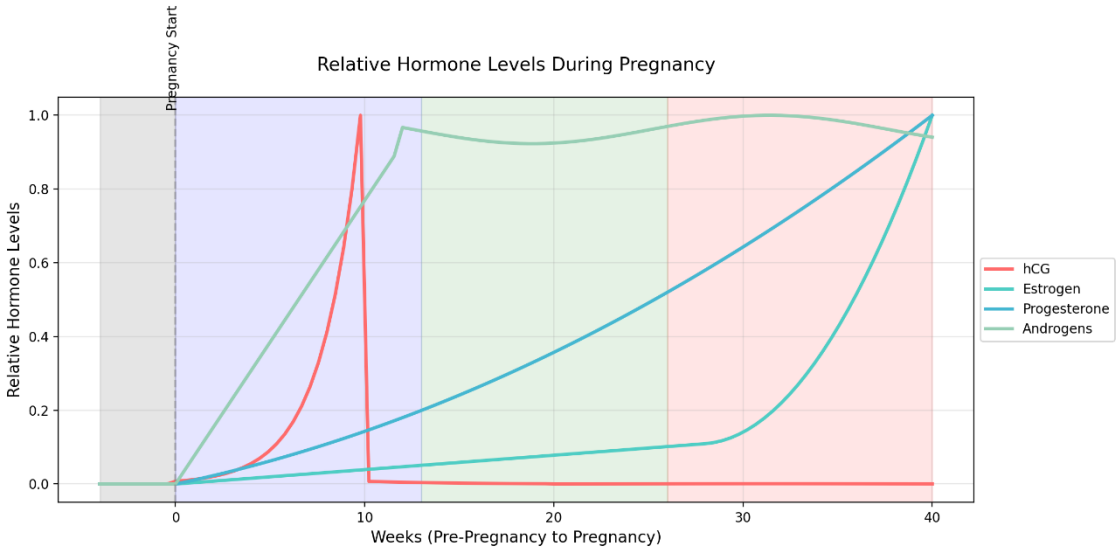


Figure 1: Relative Hormone levels during pregnancy (Author's creation)

HUMAN CHORIONIC GONADOTROPIN (HCG)

The hCG is one of the first biochemical signals that can be detected a soon as embryonic cells exist. In pregnancy, the hCG is detected approximately eight days after ovulation and one day after implantation is produced. Consequently, is detected in maternal blood before knowing the cease of menstrual cycle (14,16).

It is a fundamental hormone to avoid corpus luteum regressing, maintaining progesterone secretion by the granulosa cells until the placenta is formed (14,16). Around 8th week there is a peak on hCG levels (100IU/L) and they keep falling pregnancy finishes. (14).

OESTROGENS

Human pregnancy is a hyperestrogenic state that increases as pregnancy progresses (17). Oestrogen synthesis during pregnancy, is produced in the corpus luteum until 8th week, as progesterone, when fetoplacental transition occurs. The placenta needs steroidal precursors produced by fetal adrenal glands, because of the lack P450c17 enzyme, what makes it unable to use cholesterol as oestrogenic precursor (14,16,17). Maternal plasma estradiol levels increase, reaching 20-30ng/mL (14).

In terms of performance, they are thought to have anabolic effect specially in muscle, and evidence describes it is important in glycogen storage and fat metabolism. In addition, neuroexcitatory effect of oestrogens have been described, with possibilities to enhance muscular performance and high intensity performance (15).

The biological functions of oestrogens during pregnancy are (14):

- Induces uterus' muscle fibres hyperplasia and hypertrophy, gaining blood-flow.
- Opposite action to progesterone, stimulating adaptation for triggering the partum. Increasing myometrial excitability to favour contractions and cervix dilatation.
- Stimulating prostaglandin production and secreting.
- Stimulating growth of mammary ducts and block prolactin action

PROGESTERONE

The progesterone hormone is required to maintain gravidity specially in the first trimester. (14) It is produced in the corpus luteum until 8th week, were the placenta takes main role on progesterone secretion (14,16,17). Progesterone levels for term delivery are around 100-200ng/mL (16). The synthesis in the placenta, needs to use maternal LDL-cholesterol, turning it into pregnenolone and subsequently in progesterone (14,17).

As for performance, anti-oestrogenic effects have been described, so it has been concluded that more than oestrogenic levels, high oestrogen-progesterone ratio would enhance performance (15)

Among the biological actions of progesterone during pregnancy there are (14):

- Prepares and maintains endometrium for implantation and allows trophoblast and fetus tolerance, inhibiting local immunity system.
- Main substrate for fetal glucocorticoid and mineralocorticoid production.
- Maintains pregnancy and relaxes myometrium until partum. Is the most important inhibitor factor of myometrium activity.

ANDROGENS

Androgenic activity is increased during pregnancy. This increase is not explained by a lower clearance due to binding to sex hormone binding globulin, it seems there is also more production (17). The placenta produces testosterone since first trimester, and serum levels and three times bigger at the end of pregnancy (18).

The evidence describes the main functions of androgens during pregnancy, and they conclude that apart from being the main precursor for oestrogenic synthesis, it affects on the placenta and pregnancy development. In addition, elevated androgen are related to pregnancy complications as polycystic ovary syndrome (PCOS) (18).

Independently from genre, androgens have shown to develop muscular mass and strength in athletes. That’s why exogen androgens have been prohibited by World Anti-Doping Agency (WADA) (19).

ELITE SPORT

Literature defines elite athletes as those who highlight with good results or have the potential to do so (20). Some other authors stablish that elite sports, is the highest level of competition, from national to world-level competitions (21). Most of them are in accordance that elite sport is a dynamic interaction between genetics, environment and training (22). Psychological view of work, obsession and motivation takes great importance in some articles (23).

From these definitions, one of the major debates arise: ¿genetics or work? Tucker and Collins suggest in their article that sport performance in elite athletes is multifactorial (24). Even more, Dr. Anders Erickson speculates about the future, suggesting that using genome and training, statistical models will find potential winners (25).

SPORT RECOMMENDATIONS DURING PREGNANCY

The physical activity is beneficial for maternal and fetal health, among others, reducing risk of hypertension and gestational diabetes mellitus. Partum complications are reduced and allow the pregnant to maintain adequate fitness for the process (26,27).

The American College of Obstetricians and Gynecologists (ACOG), suggests 30 minutes of physical activity every day, as long as there is not obstetrical problems (28,29). The WHO recommends 150 minutes weekly, combining aerobic exercise, strength training and stretching, and pelvic floor strengthening. In Spain just 20.3% of women meets ACOG recommendations (26).

Recommendations stick to aerobic activities like walking, running, cycling and swimming. In the other hand, sports with trauma risk or articular injuries are discouraged, neither does in supine position or diving is needed. According to intensity, guidelines conclude moderate activities between 60-90% of max heart rate are suitable (29).

This recommendations for general population, are not adapted to elite sportswomen requirements (30). Thats why in 2016-2017 the expert group from International Olympic Committee (IOC) created specific guidelines. These recommendations explain that there is not contraindication for exercise, in general guidelines follow same statements as for recreational. But there is consensus that, elite athletes will require exhaustive obstetrical monitoring to evaluate risks (31)**.**

Last narrative review, following the contraindications to aerobic exercise during pregnancy that IOC proposed, concluded and expanded what exposed in Table 1 (32,33).

	Pre-existing Medical Conditions	Pregnancy-Related Conditions
Absolute (conditions posing high risk to fetus)	Haemodynamically significant heart disease (acquired/congenital) Uncontrolled arryhthmia Severe respiratory disease Uncontrolled T1DM ⁼ Poorly controlled hypertension ^ Severe anaemia ^Δ	Placental abruption FGR in current pregnancy Vasa praevia Cervical insufficiency/cerclage Severe pre-eclampsia PTL during current pregnancy Severe anaemia ^Δ Persistent bleeding in 2nd/3rd trimesters ^Δ Multiple gestation with risk of PTL ^ Severe anaemia ^Δ
Relative (conditions posing moderate risk to fetus)	Mild respiratory disorders Mild congenital or acquired heart disease Well-controlled T1DM Untreated thyroid disease Symptomatic, severe eating disorder Multiple nutrient deficiencies and/or chronic undernutrition Orthopaedic limitations ^ Poorly controlled seizure disorder	Mild pre-eclampsia Preterm prelabour rupture of membranes * Placenta praevia > 28 weeks' gestation * Previous fetal growth restriction, miscarriage, PTL or preterm birth ^Δ
No longer considered contraindications according to Meah et al. [39].	Chronic hypertension Recurrent miscarriage Epilepsy Anaemia Hx of spontaneous PTL Hx of previous FGR	Pregnancy-induced hypertension Short cervix Multiple pregnancy

* denotes considered to be absolute contraindication by IOC. ⁼ denotes considered to be relative contraindication by IOC. ^Δ denotes only considered to be contraindication by IOC.

Table 1: Contraindications to aerobic exercise during pregnancy: ICO; International Olympic Committee, FGR; intrauterine growth restriction, PTL;preterm labour, T1DM; type 1 diabetes mellitus **(32)**

International Olympic Committee announced the following warning signs to stop exercising described in Table 2. They also recommended to profesionals assesing elite athletes with risk for exercising to use Physical Activity Readiness Medical Examination (ParMed-X) for Pregnancy, Annexe 1. (34)

Table 2: Warning signs to stop exercising: This table has been developed based on information sourced from the guidelines issued by the International Olympic Committee (IOC) (34)

Warning signs to stop exercising:	
• Vaginal bleeding • Regular painful contractions • Amniotic fluid leakage • Dyspnoea prior to exertion • Dizziness/syncope	• Headache • Chest pain • Muscle weakness • Calf pain or swelling

MONITORING ELITE-ATHLETES

L'Heveder et al. (2022) proposed the following guidance described in Figure 2 to facilitate obstetricians to manage elite athletes during pregnancy. (32)

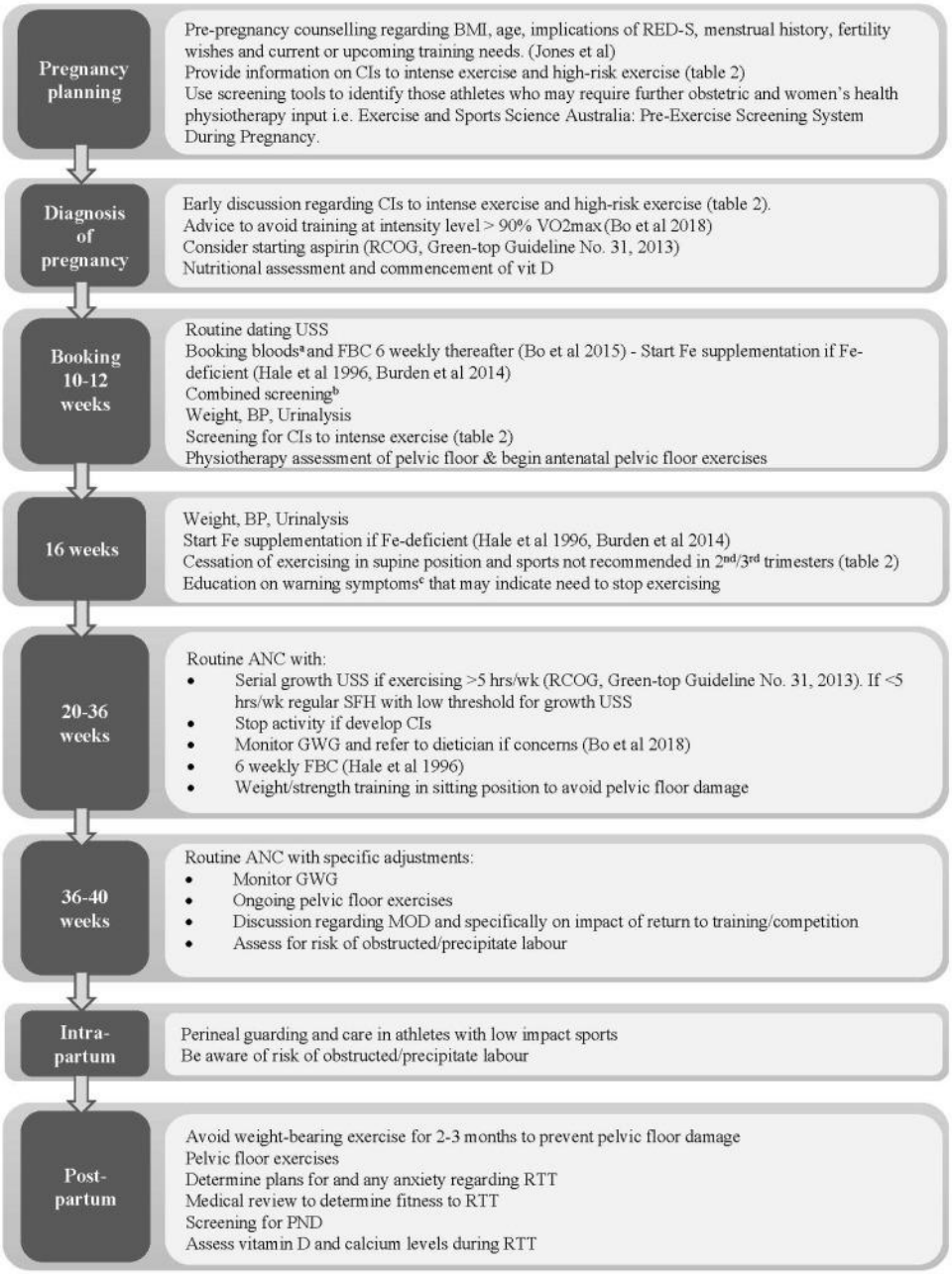


Figure 2: Guidance for obstetricians managing athletes during the preconception, antenatal and postnatal periods (32): ANC; antenatal care, BP; blood pressure CI; contraindication, FBC; full blood count, Fe; iron, GWG; gestational weight gain, hrs/wk; hours per week, MOD; mode of delivery; PND; postnatal depression, RED-S; relative energy deficiency in sport, RTT; return to training; USS; ultrasound scan, VO2 max; maximum oxygen consumption. [a] Booking bloods; FBC, Group and save, Syphilis, Hepatitis B, HIV, urea & electrolytes, glucose, iron studies, B12, folate [b] Combined screening; Nuchal Translucency (NT)/Pregnancy Associated Plasma Protein A (PAPP-A)/hCG.

COMPLICATIONS OF PREGNANCY IN SPORTS

High-intensity exercise during third trimester seems to be safe, but as for first and second trimester there is lack of evidence about intensities above 90%. Athletes tend to maintain high intensities during pregnancy, so it is necessary to be followed up and supervised continuously to avoid complications (35).

Fetal complications

There is the theory that high body temperatures, overcoming 39.2°C, have teratogenic effects. But studies have not found this significant temperature increase during exercise. But they suggest to avoid extreme climates or dehydration, that could make athletes to achieve those temperatures (28,29).

It has been documented elevation of fetal heart rate during exercise, but evidence shows that this increase is not significant to produce fetal hypoxia or complications (28). Regarding high intensity, it could reduce uterine blood flow and produce transitory hypoxia for the fetus, but there is not clear adverse effects (32,36).

Guidelines suggest relation between intense exercise, deficient diet and minor intrauterine growth, but they remark that adequate caloric intake avoids diminutions on fetal birthweight (37). Evidence about fetal growth is not conclusive in elite sports (32,38).

Pre-eclampsia

In recreational exercise, evidence says that risk to hypertensive pathologies is reduced during pregnancy. But in elite sports with high training volume, it seems to be an augment of severe pre-eclampsia (32,38). It is considered a potential danger in pregnancy, so athletes with this pathology must be controlled exhaustively (34).

Gestational diabetes

Athletes have more ability to endure metabolic stress during pregnancy. Evidence concludes that exercise is a protector factor for gestational diabetes, a dose-response effect have been described. But for high intensities in elite sports, this association disappears (38). But the reduced risk to have gestational diabetes is evidenced (34)

Premature birth

Literature had related premature birth with exercise, because of the increased catecholamines, that could stimulate myometrium contraction. But evidence in studies have shown that preterm birth incidence does not increase when exercising (39). Even so, some studies related to heavy lifting and excessive standing have been shown to be more likely to have preterm birth (34)

In the other hand, some authors have described that physical activity could be a protector factor in recreational sport, although in elite sport evidence is not conclusive (38).

Musculoskeletal injuries

Elite athletes have more risk for joint injuries due to increased laxity (28,31). Hormonal changes with high oestrogen and relaxin levels, is associated to lower back and pelvic pain (28). As for pelvic floor dysfunctions, pregnant athletes have not lower risk than sedentary women to have urinary incontinence, so doing specific strengthening exercises is recommended. (34)

Evidence describes sportswomen are more likely to suffer stress fractures postpartum (32).

Gestational weight-gain

Weight- gain is another possible complication during pregnancy. High intensity and long training seem to reduce the weight the pregnant athlete is winning, and is associated with lower fetal birthweight (28).

Athletes, as they normally are in down range of body mass index (BMI), they can have difficulties on gaining weight in a proper way, and this could be a problem for fetal growth. There is no enough evidence in elite sportswomen about relationship between weight-gain and fetal growth, when calorie intake is controlled (38).

Adequate gestational weight-gain must be used as first line indicator to decide if energy intake is enough for fetal wellbeing and development. Following that purpose, doing more frequent ultrasound control is recommended. (34)

ENDURANCE SPORT PERFORMANCE

Performance in endurance sports in mainly determined or predicted using the following three factors: Maximal oxygen consumption, lactate threshold and efficiency. The first two factors describe how much oxygen uptake can the athlete maintain in a period of time. In the other hand, efficiency stablish how much strength is made in a specified oxygen consumption (40).

Aerobic exercise during pregnancy have shown that it can maintain even increase sport performance. But focusing on elite pregnant athletes, evidence suggests that they could have better performance, but the effect of cardiorespiratory changes in VO_{2max} is not conclusive (32,41).

It seems that anaemia, changes on gravity centre, gaining weight and joint latitude could be limiting performance in sports and elevating injurie risks. Apart from physically, pregnant athletes, have to face sociological, economical and routine changes that can affect their trainings and competitions. (32)

Hormones like androgens could also play an important role in pregnancy. The androgens have been related to muscle mass and strength, and this could increase sport performance, but this needs to be more investigated (42).

In this study, we will define sport performance in adequate or not adequate depending on the measuring of VO_{2max} and muscle strength. Gestational weight-gain will also be registered, because VO_{2max} and muscle strength measured by vertical jump, both have weight factor included. To obtain blood and hormonal data, a hemogram and progesterone, oestrogen and androgen levels will be measured.

MAXIMAL OXYGEN CONSUMPTION (VO_{2MAX})

VO_{2max} is defined as the maximum capacity to use oxygen during exercise. Scientific literature, uses this variable as the main one to indicate cardiorespiratory capacity (43). In endurance sports, oxidative metabolism is the main source of energy and the performance in these sports is limited by the quantity of oxygen that the organism can absorb, transport and use. As the intensity gets harder, oxygen consumption increases, reaching a plateau where a limiting factor exists, this is the value of VO_{2max} (44).

The limiting factors that have been described are the following: Pulmonary diffusion capacity, maximal cardiac out-put, blood capacity to transport oxygen and circulation in skeletal muscles (43,44).

Evidence describes women maintain their exercise during pregnancy, have similar VO_{2max} postpartum comparing to their prepartum values. It has to been considered, that elite athletes, can reach to have VO_{2max} over 70 mL/kg/min (34). Some studies use as inclusion criteria for elite sports in women, values over 55 mL/kg/min (45). As for deciding whether measured VO_{2max} levels are adequate for performance, a 10% reduction will be considered as Performance Loss, and consequently stopping competition and intense training will be recommended.

MUSCLE STRENGTH

Muscle strength is the capacity to exert force on an object, and it have been related to greater sport performance and less injurie risk. In most of endurance sports, strength is used to face gravity and move bodyweight (46).

To evaluate muscular strength in complex movements is difficult, evidence suggests the use of vertical jump as index for muscle strength in lower extremities (47,48). Vertical jump is related to bodyweight, so it is more reliable index than muscle strength considering to evaluate endurance sports performance, where bodyweight could be limiting factor. (32) Usually, a platform is used to measure time in air of the jump of each athlete.

With this time in air, jump-height can be calculated with the following equation:

$$1/8\ [g \times t^2]$$

Being *g* gravity acceleration and *t* time in air. (48) As for Performance Loss, 10% reduction of height will be considered.

GESTATIONAL WEIGTH-GAIN

There is a physiological weight gain during pregnancy, mainly due to the fetal weight but also due to the increase of liquids and lipid tissue. This augment is produced mainly in the second and third trimester, and it can reach to 11.5-18kg in women with BMI of <25 (49).

These changes could affect the athlete's capacity to exercise in high intensities, decreasing sport performance (32). Additionally, taking in to account that body weight has direct impact on VO_{2max} (45) and vertical jump (48), measuring this variable will be important.

JUSTIFICATION

In recent years women participation in elite sports has increased significantly. There is clear evidence about beneficial effect of physical activity during pregnancy, but recommendations are limited for elite female athletes (32).

The most suitable fertility age in women overlaps with the peak performance of many athletes, making reproductive planning complicated (31,32). The idea of postponing pregnancy when sport performance decreases, will also have an effect on the reduction of reproductive capacity and the increased obstetric risks (32).

The main concerns from elite athletes are: how pregnancy affects on their sport performance, and at the same time, how training and competition impact on their fetus (28).

Literatures has mainly focused on the influence of exercising in pregnancy, but sport performance has been neglected (32). Articles seem to conclude, sport performance does not fall on the first months of pregnancy, in view of the fact that cardiovascular adaptations appear. However as gestation progresses, weight gain, anaemia and joint laxity could have an effect on performance (28,32). Furthermore, some articles describe the possibility of early-pregnancy changes being beneficial for sports (39).

There is lack of evidence about the complications of pregnancy in elite sports. Mainly because of little number of studies, but also to the fact that research has been centred on analysing the effects of high-intensity exercise just in recreational sportswomen. Overall, moderate physical activity during pregnancy is safe. Therefore, elite athletes would have to adjust intensity and type of activity they do, and have an exhaustive obstetrical tracking (32).

The objective of this study is to conclude how far can pregnant athletes maintain their sport performance, to decide on stopping competition provisionally and like this avoid possible pregnancy complications.

HYPOTHESIS

Elite endurance athletes cannot maintain their sport performance until the beginning of second trimester of pregnancy.

SECONDARY HYPOTHESIS

- Physiological changes in pregnant elite endurance athletes do not produce significative VO_{2max} gains in first weeks, and it is reduced progressively throughout the weeks.
- Hormonal changes, as androgen level increase, can enhance muscular strength in the first weeks of gestation in pregnant elite endurance athletes.
- The older the maternal age, the earlier the performance decline occurs.
- The Time to Performance Loss during pregnancy can change depending on ethnicity.
- The practiced Type of sport can influence the Time to Performance Loss; running sports are more likely to have shorter Time to Performance Loss.
- Bigger pre-pregnancy maternal bodyweight facilitates the lengthen the Time to Performance Loss.
- Lower pre-pregnancy maternal Body Mass Index (BMI) makes adaptations to pregnancy more difficult, shortening Time to Performance Loss.
- Gestational weight-gain is directly related to Time to Performance Loss, the bigger the gestational weight gain is, the shorter Time to Performance Loss.
- Elite endurance athletes with previous obstetrical problems described on TPAL formula, are more likely to have obstetrical complications during pregnancy.

MAIN OBJECTIVE

The main objective of the study is to analyse how pregnancy affects on sport performance in elite endurance athletes, by determining the time to 10% of performance loss, assessing VO_{2max} and muscle strength.

SECONDARY OBJECTIVES

- To analyse how pregnancy early cardiorespiratory physiological changes affect $VO_{2max,}$ in elite endurance athletes.
- To analyse how hormone changes, especially androgen augment, affect on muscular strength and consequently in vertical jump, in pregnant elite endurance athletes.
- To analyse how different maternal age respond to pregnancy in terms of Time to Performance Loss in elite endurance athletes.
- To analyse how different ethnicities respond to pregnancy in terms of Time to Performance Loss in elite endurance athletes.
- To analyse how different Type of sport respond to pregnancy in terms of Time to Performance Loss, in elite endurance athletes.
- To analyse how different pre-pregnancy maternal body weight respond to pregnancy in terms of Time to Performance Loss, in elite endurance athletes.
- To analyse different pre-pregnancy maternal Body Mass Index (BMI) respond to pregnancy in terms of Time to Performance Loss, in elite endurance athletes.
- To analyse how gestational weight-gain during pregnancy relates with Time to Performance Loss, in elite endurance athletes.
- To analyse how previous TPAL formula is related with obstetrical complications during pregnancy, in elite endurance athletes.

METHODOLOGY

STUDY DESIGN

To accomplish the main objective, a single-arm multicentre cohort study will be performed. The study has been designed to analyse how does pregnancy impact on the sport performance of elite endurance athletes, to enable estimations of time to drop performance and consequently stablish recommendations to stop competing.

STUDY SETTING

Member Doctors from different National Associations of Sports Medicine, and doctors belonging to professional or national teams will be performing the recruitment and data collection. As population to analyse is really reduced study must be done internationally, every doctor could follow their specific elite athletes willing to get pregnant if they get included in the study. Every Doctor will need to ensure that methods are being followed correctly.

Database Website in Research Electronic Data Capture (REDCap) has been created to facilitate Doctors the procedure of the data collection in the study.

STUDY POPULATION

The study population for this study will be endurance sport elite level athletes (that would like or are planning to get pregnant).

PARTICIPATION CRITERIA

Inclusion Criteria:

- To be considered as an Elite Athlete, one of the following items will be needed:
  - Participation in the Olympic games
  - Participation in World Championships
  - Participation in Continental Championships
  - Being 1st, 2nd or 3rd in National Championships
  - Being part of a team/league in the highest level of the sport
- To be actively competing in elite level in endurance sport at recruiting time
- Included participants will need to have the will to get pregnant
- Age range 18-35

Exclusion Criteria:

- Infertility
- Participants not able to get pregnant in 9 months from the first data collection
- Athlete involved in WADA examination or previous use of non-accepted drugs
- Not being able to do required tests (e.g. injured athletes, wheelchair athletes…)
- Using oral contraceptive methods 3 months before the pre-pregnancy testing start.

Withdrawal criteria:

- Not being able to follow training or not being able to complete required tests.
- Not completing study requirements and follow-up.
- Participants with medical conditions contraindicated in Table 1 will be registered and they will finish their study.
- Ectopic pregnancies or other complications.
- Athlete involved in a new WADA examination during the study or evidence of previous use of non-accepted drugs.

As for data collected until withdrawal criteria are met, will depend on the specific criterion. Not being able to follow training or required tests will be considered as Performance Loss and the data until that date will be used.

For participants not completing the study follow-up, the data until the date will be used, but Performance Loss will not be specified.

Participants that develop medical conditions contraindicated in Table 1, will be registered as obstetrical problems in data website and Performance Loss will not be specified.

As for ectopic pregnancies or any other specific obstetrical complication not referred in Table 1, participant's data will not be considered. For athletes with WADA examination during the study period, will be automatically considered as invalid data.

SAMPLE SIZE

Calculus of the sample size have been done with Datarus Granmo web application. Population Estimation mode has been used to ensure sample size is correct.

For reference population, pregnant elite athletes per year have been considered. This has been estimated having around 100.000 women elite athletes and considering around 1% of them gets pregnant in a year. This gives 1000 pregnant elite athletes per year as reference population.

For stablishing standard deviation, literature does not talk about Time to Performance Loss standard deviation. Specialists in sports medicine have recommended to use 5 weeks for calculating.

A sample size of **97** subjects randomly selected will suffice to estimate with a 95% confidence level and a precision of +/-1 units, a population mean of values with an estimated standard deviation of 5 units. A substitution rate of 10% has been anticipated.

To ensure sample size is correct, once data of 20 subjects have been registered, standard deviation will be stablished, and sample size will be recalculated with the new standard deviation. If previous sample size is not enough, recalculated sample size will be used.

SAMPLE SELECTION

Sports doctors worldwide will be able to select athletes for the study. As population is really reduced, the doctors will need to include participants by consecutive sampling.

Getting pregnant is something that could not be decided by randomization. Elite athletes do have close relationship with their doctors, even more in they are into reproductive planification. Athletes have the need to inform their sports doctor about their will to get pregnant, and this is when the professional will propose them to enter in the study.

DATA COLLECTION

Before any data collection, participation information sheet and informed consent should be given and signed by the athletes, following Annexe 2 and Annexe 3 respectively. For data collection it is important to align visits with the last date of period, recommended to be the first day after finishing menstruation. Data will be collected by each doctor in Research Electronic Data Capture (REDCap) website database created for this study.

First day of data collection, the athlete will need to complete the form in Annexe 4, containing full name, medical record number and contact information.

Additional data will be directly registered in REDCap for confidentiality: ethnicity, TPAL formula, Type of sports and height.

The testing will be performed always in the following order of preference: Blood analysis, Pregnancy test, Body weight measurement and height, PAR-MedX for Pregnancy (Annexe 1), Vertical jump test and VO_{2max} test.

Pre pregnancy, VO_{2max} will just be measured once in the first visit for reference value. Every 2 weeks, blood analysis, pregnancy test, Vertical jump test will be performed. If the athlete does not get pregnant in 9 months, it will not be included in the study.

The day pregnancy test turns positive, the following data collection will be performed and registered: Blood analysis, Body weight measurement, PAR-MedX for Pregnancy, Vertical jump test, VO_{2max} test.

From here on, every 2 weeks tests will be performed and registered: Blood analysis, Body weight measurement, PAR-MedX for Pregnancy, Vertical jump test and VO_{2max} test.

Last data collection will be considered when: Performance Loss, meeting Withdrawal criteria or when arriving third trimester.

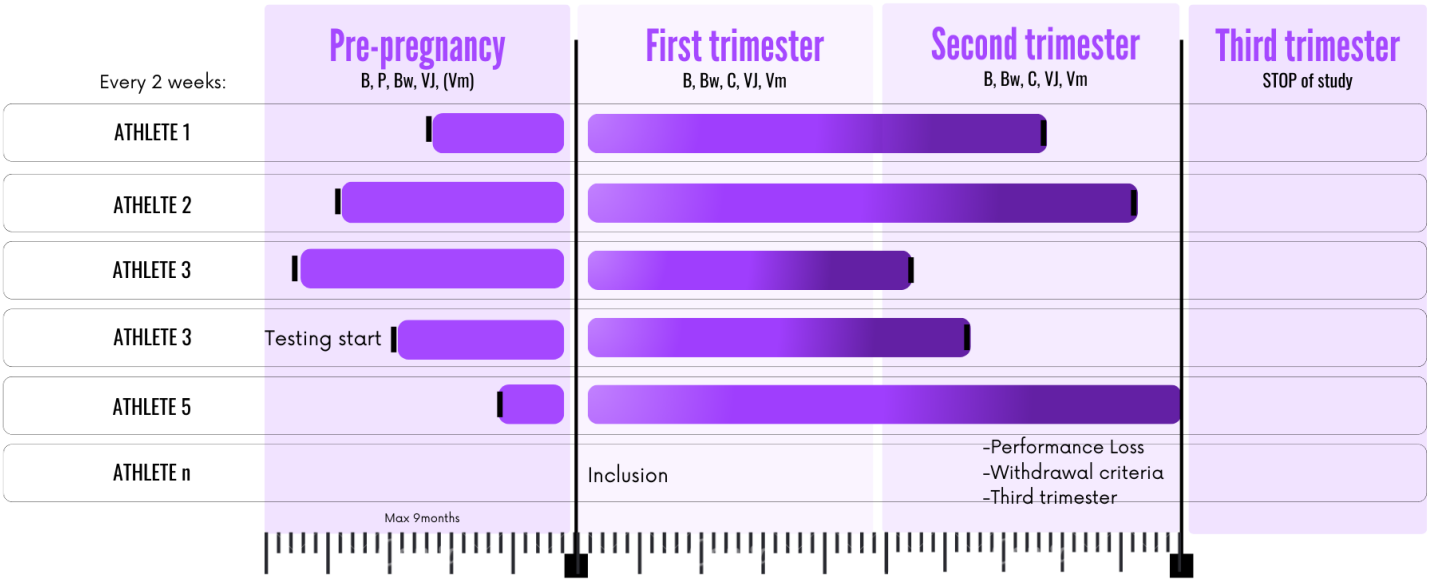


Figure 3: Example of chronogram of data collection: B; blood analysis, P; pregnancy test, Bw; body weight, VJ; vertical jump test, Vm; VO_{2max} test, C; Complications detection with PAR-MedX for Pregnancy. Note: VO_{2max} test pre-pregnancy just in first visit.

To test if athletes are pregnant, a pregnancy test will be performed every data collection until positive test. HCG immunoassay has been the test with highest sensitivity and convenience. Urine can reveal positive result 3-4 days after implantation, 98% will be positive after 7 days. (50) Once test is positive, we assume 4 weeks of gestation, because last period date is used for counting gestational weeks.

Data collection pre-pregnancy, containing pregnancy test, will be performed every 2 weeks. Athletes will need to consider their period lasting day to allow doctors start data collection according to it. Data collection and menstrual cycle will have to be aligned, performing data collection the day after period finishes. Last period day will be considered as Estimated Date of Conception (EDC) when hCG test turns positive. Pre-pregnancy (week 0) data collection will be the one immediately after the EDC. Positive test day will be considered as Week 4 and the intermediate one will be Week 2, illustrated in Figure 4.

Any test performed by athletes by their own won't be accepted, and the next day of data collection hCG test will be performed to be considered the positive test day.

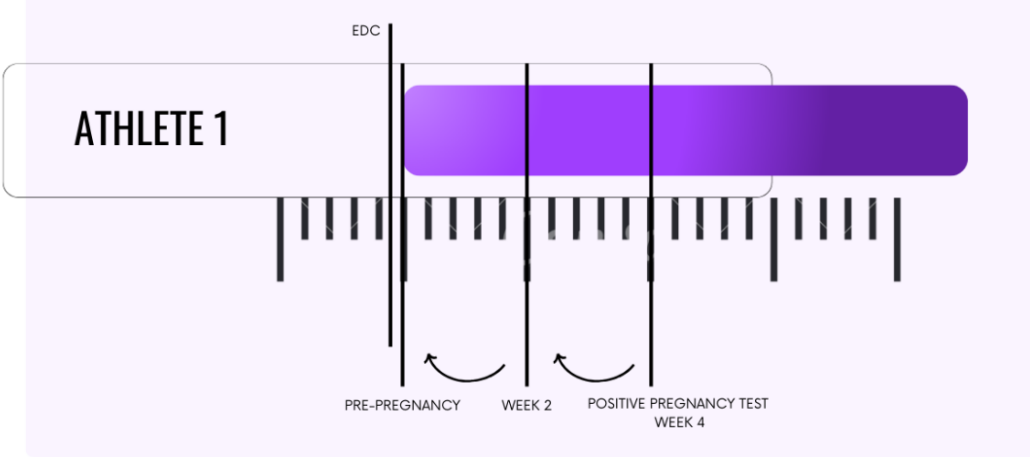


Figure 4: Stablishing Pre-pregnancy data collection day

All the data will be collected as described in the Reference Data Collection Table in Annexe 3, in order to ensure every athlete data collection is homogenous.

To facilitate data collection, 20 Force platforms have been added to the budget. Jump testing is not as frequent and accessible as the other equipment needed for the study, that is why it has been implemented into the study budget. This equipment will be sent to correspondent Doctor's Clinics to ensure calibrated equipment is used, and none of the athletes can't afford to test correctly.

As for VO_{2max} testing and body weight measuring, it will be preferably tested in a Bodytone Dt18+ running treadmill and Tanita BC-545N respectively, but as it is an international study homologated testing machines regularly used in Sports Clinics could be accepted by researchers' criteria.

VARIABLES

DEPENDENT VARIABLE

TIME TO PERFORMANCE LOSS

Every data collection will have to register the date performed: year/month/day.

As for Performance Loss, any of VO_{2max} or Muscular strength falling 10% will be considered as fall of 10% of sport performance. Marginal differences become very important on elite sports, and this percentage would be enough to avoid getting to the podium.

If an athlete has obstetrical complications named in Table 1, meeting withdrawal criterion, data will not be used. Not being able to complete required performance test will be considered as Performance Loss.

With these dates, the exact gestational week when performance loss will be registered and the time since pregnancy starts will be calculated: (e.g. 88 days). It will be calculated with the following formula:

Estimated Date of Conception – Date of Performance Loss = Time to performance Loss

INDEPENDENT VARIABLES

HORMONE LEVELS

In the blood analysis, hormone levels will be quantified. Every Doctor in the study will need to have a reference laboratory to do the analysis. The determination of hormonal levels will need to be made by **ELISA assay**. Every analysis data will need to be uploaded to the data website with the laboratory report. All the hormonal levels will be specified in ng/mL. The analysis will need to contain at least the following hormonal items:

- Serum Progesterone (P4)
- Estradiol (E2)
- Estriol (E3)
- Sex Hormone-Binding Globulin (SHBG)
- Total Testosterone
- Free testosterone
- Dehydroepiandrosterone Sulphate (DHEA-S)
- Free Androgen Index (FAI)

VO_{2MAX}

The Maximal oxygen consumption will be registered using gasmask monitorization, preferably **Quark CPET**, in a running treadmill, preferably **Bodytone Dt18+** running treadmill or accepted and calibrated gasmask and treadmills used in Sports Clinics.

Gas monitoring devices normally give VO_{2max} results in mL/min, in order to equate different body sizes, maximal oxygen consumption will be specified in mL/min/kg. VO2max will be considered when VO2 plateau is reached, when increased workload.

It will need to be a continuous gas monitoring device, to ensure VO_{2max} values detected are correct and acceptable during the incremental test. Depending on the type of sports of each athlete and pregnancy, the capacity to run could change, that is why regular running treadmill protocols do not fit the population of study.

For reaching VO_{2max} values, an incremental test will be performed for the athletes. The Modified Bruce test will be the protocol followed for testing VO_{2max}, explained in Table 3. It has been modified by Sports Doctors in Catalonia to reach VO_{2max} levels faster and more efficiently for pregnant women. It will be composed with a warming-up period, testing period with incremental stages and rest period.

Warm-up period it is established to 3 minutes in 6km/h and 0% incline. Incremental testing stages will change every minute, they will increase 0.5km/h and 2% of incline. Resting period, considered 1minute at 4km/h pace and 0%incline, will start when VO_{2max} plateau is achieved or volitional fatigue.

Table 3: Modified Bruce Protocol

Phase	Time	Speed	%
WARM-UP	3:00	6	0
STAGE 1	1:00	6	6
STAGE 2	1:00	6.5	8
STAGE 3	1:00	7	10
STAGE 4	1:00	7.5	12
STAGE 5	1:00	8	14
STAGE 6	1:00	8.5	16
STAGE 7	1:00	9	18
STAGE 8	1:00	9.5	20
STAGE 9	1:00	10	22
STAGE 10	1:00	10.5	24
STAGE 11	1:00	11	26
ACTIVE REST	1:00	4	0
REST		0	0

MUSCLE STRENGTH

As explained above Muscle Strength will be determined by Vertical jump. To collect data for vertical jump a force platform **Plyomat Switch Mat Portable 28"x14"** is recommended (51). As being elite athletes, there is high probability of them having done this test before, but it must be ensured to follow protocol correctly, so the test must be done by an evaluator. Will be performed by the following indications:

Before starting measuring, an standardize warming-up will be done. Consists of 10 minute warm-up, including low intensity aerobic exercise, dynamic stretching and one set of 6 sub-maximal jumps. (52)

Athlete will perform the jump without shoes, socks allowed, and adequate clothing for testing. Stance position in the platform should be appropriate for each athlete to be able to squat and do the following jump, shoulder-width stance position is recommended. To perform the jump Akimbo style (Figure 5), hands must be on the waist, to avoid balancing that could change height of the jump. Once athlete and evaluator are prepared, the order to start a slow squat will be given. The squat needs to get 90º knee flexion, to be considered as correct. The evaluator will give indication to jump when this flexion is considered achieved. Regarding to the landing, must be performed with feet in neutral position and knees on extension or slight flexion to absorb the impact.

The measuring of vertical jump will be measured 3 times, with 2 minutes rest between jumps. Vertical jump will be performed just after measuring body weight, and before doing VO_{2max} testing. Time in air and height are calculated and registered, being time in air and jump height proportional. Just the highest value will be considered and registered for data, using cm as unit. Will be important to measure at same place, force platform, time and conditions.

Figure 5: Manner of Performing Countermovement Jump-Akimbo Style (53)

COVARIABLES

AGE

Maternal age when Estimated Date of Conception will be registered in years.

ETHNICITY

Ethnicity will be registered with “ethnic_group_tb_6a” categories from Census 2021 (Office for National Statistics).

Code	Name	Code	Name
1	Asian, Asian British or Asian Welsh	4	White
2	Black, Black British, Black Welsh, Caribbean or African	5	Other ethnic group
3	Mixed or Multiple ethnic groups	-8	Does not apply

TPAL

Obstetrical TPAL formula will be registered in the first visit. It will be recorded as a 4 digit number (e.g. 1011). Representing in order; Term births, Preterm births, Abortions, Living.

From this number, taking into account whether the second or third digit is bigger than 0, it will be classified as Yes. On the other hand, if both digits are 0 will be classified as No.

This variable will be dichotomous:

- Yes
- No

TYPE OF SPORT

Sport of the athletes will be registered in the first data collection, with the following categories:

Code	Name	Code	Name
R	Running-based	S	Swimming-based
C	Cycling-based	O	Other: Register specific sport

Note: Multisport disciplines (e.g. triathlon) enter in “Other” category.

BODY WEIGHT

Maternal body weight will be registered every data collection in Kg unit. The measurement will be done in **Tanita BC-545N** weight scales or calibrated and accepted weight scales in clinics. The procedure must be done at the same time of the day and in same conditions, and calibration must be done annually. Weight must be registered no shoes and with just underwear, in a flat surface.

HEIGHT

Height will be measured with a measure tape in meters.

BODY MASS INDEX (BMI)

Body mass index will be calculated out of body weight and measuring the height of the athletes. Body mass index will be calculated automatically in database and included in a group. This groups are used for women athletes as standardized; they will be coded for data registering.

$$BMI = kg/m^2$$

Code	Name	Code	Name
1	Underweight (<18.6)	4	Moderately obese (28.8-39.9)
2	Normal weight (18.6-23.8)	5	Obese (>40)
3	Overweight (23.9-28.7)		

GESTATIONAL WEIGHT-GAIN

Gestational weight-gain will be calculated automatically in the database, kg unit, using the following formula:

$$Weight\ (Week\ X) - Weight\ (Pre\text{-}pregnancy) = Gestational\ weight\ gain$$

CONTROL VARIABLES

PREGNANCY TEST

Pregnancy test, **Abbot Alere hCG Easy Test (25mIE/ml)**, will be needed to perform every 2 weeks until it turns positive, or exclusion criteria is applied. It will be registered as dichotomous variable:

- Negative
- Positive

OBSTETRICAL COMPLICATIONS

Pregnancy related absolute and relative contraindications in Table 1 will be registered, and consequently the study of these athletes won't collect more data. They will be registered and specified as written as following:

- Placental abruption
- FGR in current pregnancy
- Vasa praevia
- Cervical insufficiency/cerclage
- Severe pre-eclampsia
- Severe anaemia
- Persistent bleeding in $2^{nd}/3^{rd}$ trimesters
- Multiple gestation with risk of PTL
- Mild pre-eclampsia
- Preterm prelabour rupture of membranes
- Placenta previa >28 weeks' gestation
- PTL or preterm birth

Any complication from Table 1 will be considered as Yes for Obstetrical complications variable. Registered as a dichotomous variable.

- Yes
- No

PAR-MedX for Pregnancy will be performed every data collection after pregnancy test turns positive to detect possible obstetrical complications.

As explained before, athletes with these conditions will be not considered as data for calculating Time to Performance Loss.

SUMMARY TABLE

Variable	Measurement	Type	Unit/Categories
Time to Performance Loss	-	Quantitative Continous	days
Hormone levels	ELISA	Quantitative Continous	ng/mL
VO2max	Quark CPET	Quantitative Continous	mL/min/kg
Muscle strength	Plyomat Switch Mat 28"x14"	Quantitative Continous	cm
Pregnancy test	Abbot Alere hCG Easy Test	Qualitative Dicothomous	Yes or No
Age	Annexe 4	Quantitative Continous	years
Ethnicity	Annexe 4	Qualitative Polytomous	1-5/-8
TPAL	Annexe 4	Qualitative Dicothomous	Yes or No
Type of sports	Annexe 4	Qualitative Polytomous	R/C/S/O
Body weight	Tanita BC-545N	Quantitative Continous	kg
Heigth	Measure tape	Quantitative Continous	m
BMI	_	Qualitative Polytomous	1-5
Gestational weigth-gain	-	Quantitative Continous	kg
Obstetrical complications	PARMed-X for Pregnancy	Qualitative Dicothomous	Yes or No

STATISTICAL ANALYSIS

To proceed the statistical analysis Statistical Package for Social Sciences (SPSS) will be used, software version 30.0.0. To describe statistical significance, $p<0.05$ will be established, and 95% confidence interval will be used.

DESCRIPTIVE ANALYSIS

To describe the sample in pre-pregnancy, quantitative variables as: Age, Body weight and Height; will be summarized using the mean and standard deviation if normal distribution, and if other distribution median and interquartile range will be used. For describing qualitative variables as: Type of sports, BMI, ethnicity, TPAL; will be resumed in frequencies and percentages.

Every 2 weeks during pregnancy, Hormonal levels, VO_{2max}, Vertical jump and Gestational weight gain; will be summarized using the mean and standard deviation if normal distribution, and if other distribution media and interquartile range will be used.

In the other hand, Obstetrical problems will be described using proportions and 95% confidence intervals.

When all the subjects finish their study, Time to Performance Loss will be calculated and summarized using the mean and standard deviation.

BIVARIANT ANALYSIS

To analyse the evolution of Time to Performance Loss, VO_{2max}, Muscle Strength over weeks, ANOVA statistical method will be used to identify differences between groups. Groups will be the qualitative variables: Ethnicity, BMI, Type of sports.

To describe the relation between Androgen levels and muscle strength during pregnancy weeks, Pearson correlation test will be performed.

A Chi-square test will be performed to describe the association between TPAL formula and Obstetrical complications.

MULTIVARIANT ANALYSIS

A linear regression model will be used to analyse Time to Performance Loss, VO_{2max}, and Muscle strength across different weeks, depending on quantitative continuous variables such as: Age, Body weight, and Gestational weight-gain

ETHICAL CONSIDERATIONS

The study will adhere to the ethical principles outlined in the Declaration of Helsinki of Ethical Principles for Medical Research Involving Human Subjects, as revised and adopted by the World Medical Association in October 2013. Furthermore, the study will be conducted in accordance with the Principles of Biomedical Ethics as defined by Beauchamp and Childress (last reviewed in 2009), encompassing the principles of autonomy, beneficence, nonmaleficence and justice.

The autonomy of every subject will be ensured, every subject will need to understand and sign Informed Consent Form. In addition, a Patient Information Sheet will be given to better understanding of the study and what it involves participating. All the data will be protected in REDCap website, and just the essential researchers will have access to personal information.

Regarding beneficence, every subject will benefit from the following up process in the study. This data collection will be additional from rutinary obstetrical revisions, so it would be beneficial for athletes to participate. It also would help population to have estimated Time to Performance Loss to, on a near future, figure out recommendations for this specific population. Adequate design has been chosen for the objective to achieve, furthermore main objective its suitable and beneficial for population.

Study will not be damaging population and there will not be considerable risks, as it is observational study and no intervention is needed. The testing done is proved to be safe even for pregnant women. The only thing could not be suitable for every person is repeated tests and follow up, but in the case of elite athlete they are used to attend Sports Doctor's appointments repeatedly, so frequency of data collection would not be uncomfortable for them. In addition, they will be used to the testing done, because they are rutinary tests for athletes.

As for justice, there will not be any discrimination on the population, fairness and equality will be followed. Furthermore, pregnant women should not be excluded from research, the lack of evidence on them is worrying. They should have equal opportunities as non-pregnant women. During testing there should not be any problem or harming, but in any case, and insurance will be hired to cover harms made specifically by the study.

LEGAL CONSIDERATIONS

This study protocol will be submitted to “Comitè d’ètica d’investigació clínica” (CEIC) in Hospital Universitari de Girona Dr. Josep Trueta. The approval of the CEIC will be mandatory for the realisation of the study. According to their criteria and objections, could lead to modify or adapt the presented study if necessary and possible. Every centre and country willing to enter the study will need to approve the protocol in their Ethical Committee, and if accepted, legislation of every country included will be followed.

In addition, the study will follow Orden Ministerial SAS/3470/2009, which rules observational studies with Medicines in Spain, but it also apply some objections for other observational prospective studies.

The procedure for other post-authorization observational studies, explained in point 7.4, abbreviated as EPA-OD, applies to post-authorization studies that are "prospective follow-up," such as case-control studies, cross-sectional studies, or retrospective cohort studies. AEMPS need to classify the study as EPA-OD, with the approval of the CEIC and the protocol summary. The study will be registered in the AEMPS and notified to authorities.

The study will have the need to use biological samples of the participants to perform the study correctly, so this must be ruled with Spanish legislation in Spain, but will need to follow the legislation of each country where the study proceeds. Before entering a subject to the study, specific legislation of every country will be verified and followed. As for biomedical investigation, the study will be ruled by the following laws, three main countries where study will be performed have been used as examples:

·Spain

- “Ley 14/2007, de 3 de julio, de Investigación biomédica.”
- “Real Decreto 1716/2011, de 18 de noviembre, por el que se establecen los requisitos básicos de autorización y funcionamiento de los biobancos con fines de investigación biomédica y del tratamiento de las muestras biológicas de origen humano, y se regula el funcionamiento y organización del Registro Nacional de Biobancos para investigación biomédica.”

·United States

- Common Rule (45 CFR 46): Basic HHS Policy for Protection of Human Research Subjects

·United Kingdom

- Human Tissue Act 2004
- UK Policy Framework for Health and Social Care Research: This policy framework sets out principles of good practice in the management and conduct of health and social care research in the UK.

All the women included in the study will sign an Informed Consent Document, attached in Annexe 3. Each member of the research team and the respective Sports doctors, will sign a statement attesting to having read, approved, and agreed to comply with the final protocol and the ethical principles governing research. The study will be following the Spanish legislation about personal data, as stated in these laws:

- "Reglamento (UE) 2016/679 del Parlamento Europeo y del Consejo Europeo, de 27 de abril de 2016, relativo a la protección de 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".
- "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".

All the data will be protected in REDCap website, and just the essential researchers will have access to personal information, ensuring confidentiality and privacy of all the participants.

Our project will be registered at the before its beginning, and its results will be published transparently. All researchers declare not having conflict of interest in any aspect of this research.

STRENGTHS AND LIMITATIONS

LIMITATIONS

This study will follow consecutive sampling method, so it will be non-probabilistic sampling, which could lead to misrepresent population with a selection bias. This could have not been solved because population is really reduced. Inclusion and exclusion criteria have been designed specifically to define target population carefully.

This cohort study is a multicentre study because of the specificity population, and this could lead to variability. Measuring methods have been stablished to follow in the protocol, but it has been accepted to use calibrated tools in specific sports centres to do the measurements. In addition, measuring equipment has been planned to buy to reduce this measuring bias.

During the study, a management agent will ensure that pregnant athletes are pleased and want to continue their data collection. Furthermore, online meetings will be planned with doctors to ensure they follow the protocol.

To calculate sample size, reference population have been stablished, and standard deviation have been estimated. This could lead to small sample size cause standard deviation is approximate. To ensure the study is accurate, protocol has stablished to recalculate the sample size once 20 participants have finished their study.

Study design being prospective, makes participation withdrawal likely to happen, but in the case of this study, professional athletes and their doctors will be interested in to doing the follow-up in to have better knowledge about their performance during pregnancy. Specific withdrawal criteria have been stablished to ensure data is not disrupted.

As for independent variable, Time to Performance Loss, it is well known that minimum changes on performance could lead to not be able to compete for winning. Percentage of Performance Loss have been stablished after reviewing the literature, not finding a consensus between studies and lack of evidence in specific population. We decided to apply the 10% as cut-off value because it is considerable, and it is likely that athletes would not have potential to win as margins in professionalism are so reduced.

Confusion bias is likely to occur as an observational study. To reduce this bias and multivariate analysis will be carried out with potential confounding variables. Uncontrolled variables as training, could be leading to bias but professional coaches will be following athletes and their training planning.

STRENGTHS

The population studied is very specific and there is a big gap of knowledge to address in this thematic. This study will help to lay the foundation for future research and will be opening wide frontiers that have not been studied until know. In addition, population will benefit from the study results. Interdisciplinary approach has been followed in the study design, involving sport doctors and obstetrical professionals.

This study has been designed specifically to assess the main objective, cohort study is the most adequate design to ensure that objective is achieved. In addition, the design gives extra data for secondary objectives and further investigation.

Standardized procedures have been stablished to measure physiological variables, despite different measuring tools have been accepted.

Data collection will be multidimensional, considering physiological variables, performance metrics and social parameters. Data will be collected securely in Research Electronic Data Capture (REDCap) to ensure security and confidentiality.

Being a multicentre study, gives wider representation of the population allowing different ethnicities to be studied. It also facilitates to get include participants as population is very reduced and will help to avoid underrepresented groups.

Ethical considerations have been strictly applied in this study, following also legal considerations in order to follow each country's legislation. Safety has been ensured with non-invasive procedures and low impact measuring of the variables.

WORK PLAN

TEAM MEMBERS

The study will have a multidisciplinary approach and support, and will consist of the following:

COORDINATOR AND MAIN RESEARCHER:

Telmo Semperena: Responsible for the elaboration of the protocol, writing conclusions and publication results. He will also have coordination responsibilities.

CO-RESEARCHERS:

·*Dr. Daniel Castillo Isern, Sports doctor:* Dr. Castillo is Sports doctor for cycling team GreenEdge Cygling and used to be Sport doctor in "Centre d'Estudis de l'Alt Rendiment Esportiu". He has helped on the study design and physiological aspects of the study.

·*Dra. Amelia Valladolid Urdangaray, Obstetrician:* Dra. Valladolid is working as gynecologist in Basurto University Hospital in Bilbao and is also teacher in UPV. She has given the study the obstetrician point of view and ethical aspects regarding pregnant women.

-*Ruth Martí Lluch, PhD, Methodology expert:* Martí has worked in Group of Epidemiology and Research in Vascular Health in Girona. She has helped in methodological aspects of the study.

Support researchers: Every doctor including their athletes in the study will have access to write their data on the REDCap website.

Management agent: Management agent will be contracted to ensure follow-up of the participants and any other aspect that could lead to complications for the study.

Statistical analyst: Statistical analyst will be contracted to do the data analysis.

STUDY STAGES

PROTOCOL DEVELOPMENT

(December 2024-January 2025)

Development of the protocol started December 2024, after doing the first meeting with main researcher and co-researchers.

Bibliographic research about sport performance, pregnancy and hormones started immediately in PubMed and Ginecology and Obstetrics' books. Additionally, it has been researched how to assess this performance to ensure standardized methods.

Protocol elaboration was performed with co-researchers, hypotheses and objectives were set, variables were described and methodology to follow was stablished.

ETHICAL EVALUATION

(January 2025-June 2025)

Protocol will be submitted to "Comitè d'ètica d'investigació clínica" (CEIC) in Hospital Universitari de Girona Dr. Josep Trueta. According to their criteria and objections, could lead to modify or adapt the presented study if necessary and possible. The main researcher and co-researchers will be responsible for this stage.

PREPARATIONS AND SPREADING

(July 2025-December 2025)

This period will be for spreading and marketing, to ensure that every athlete that wants to get pregnant or their doctors now about the existence of this study.

In addition, this period will also be useful for organization and equipment acquisition. Equipment will be sent to main centres in smaller countries to ensure the possibility of the athletes to do required tests.

INCLUSION AND FOLLOW-UP

(September 2025-December 2028)

Athletes with the will of getting pregnant, will start their data collection process, once they get positive pregnancy-test they will be included in the study.

When included, follow-up period will start until study is finished for them. 97 participants will need to be studied and followed-up during the pregnancy, which makes this period last for 3 years to be able to achieve this sample.

Each Doctor will need to follow-up their athletes, but Management agent will ensure and organise this period.

STATISTICAL ANALYSIS

(January 2029-May 2029)

Statistical analyst will be contracted as specified above, the protocol will be followed and respected. Once statistical analysis is finished, results will be discussed by the main researcher and co-researchers.

PUBLICATION

(May 2029-December 2029)

The article will be written by the main researcher and co-researchers. Once finished and revised, the article will be published as a journal article and open access.

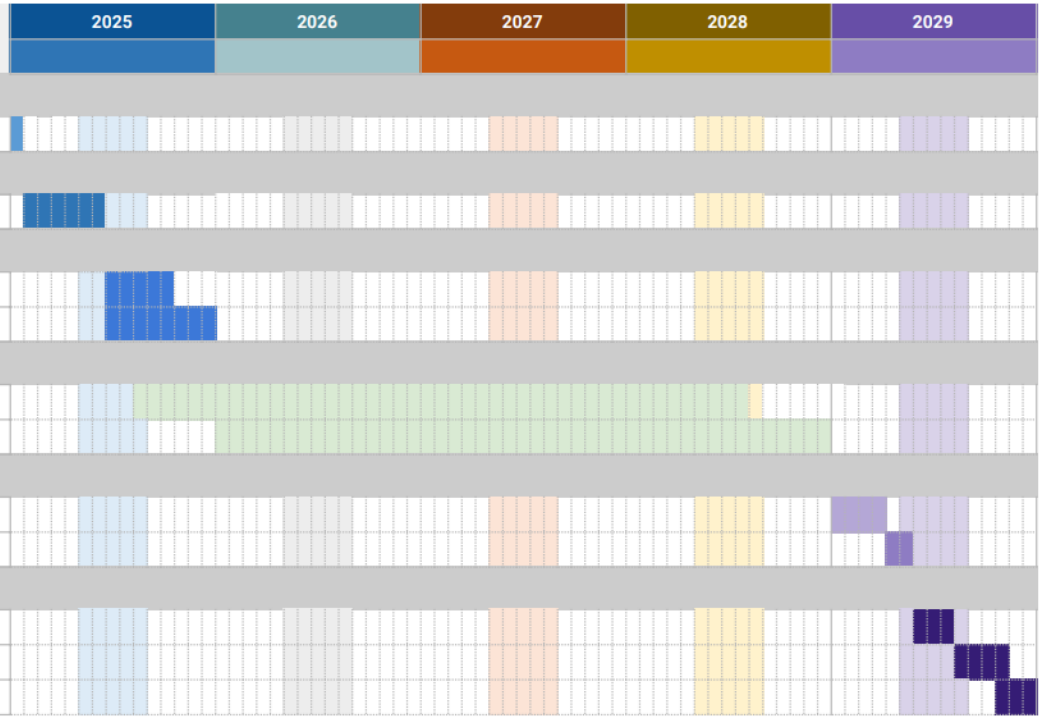
When published, there will be the possibility for the dissemination of the article will be done in social media of the researchers and participants.

Furthermore, the results will be presented at the International Congress of the Spanish Society of Sports Medicine and at the Congress on Medicine and High-Level Sports organized by the Spanish Olympic Committee.

CHRONOGRAM

RESPONSABLE DEL PROYECTO	Telmo Semperena Oyarzabal	FECHA	2025-2029

NÚMERO EDT	TÍTULO DE LA TAREA	RESPONSABLE DE LA TAREA	FECHA DE INICIO	FECHA DE ENTREGA	DURACIÓN
1	**Protocol Development**				
1.1	Protocol Development	Main Researcher	12/12/2024	25/01/2025	43
2	**Etichal evaluation**				
2.1	Ethical evaluation	CEIC	25/01/2025	30/06/2025	155
3	**Preparations and Spreading**				
3.1	Spreading	Marketing	1/07/2025	31/10/2025	120
3.2	Equipment acquisition	Main Researcher	1/07/2025	31/12/2025	180
4	**Inclusion and follow-up**				
4.1	Inclusion	Doctors	1/09/2025	30/09/2028	1109
4.2	Follow-up	Doctors	1/01/2026	31/12/2028	1080
5	**Statistical analysis**				
5.1	Statistical analysis	Statistical agency	1/01/2029	31/03/2029	90
5.2	Results discussion	Main Researcher	31/03/2029	31/05/2029	60
6	**Publication**				
6.1	Draft Article	Main Researcher	31/05/2029	1/09/2029	91
6.2	Publication	Main Researcher	1/09/2029	15/12/2029	104
6.3	Dissemination	Main Researcher	1/10/2029	31/12/2029	90



BUDGET

The budget is an approximation for the real costs of the study. We have given the study a real and feasible estimation of the budget to achieve the objectives of the study. Unexpected costs could appear during the realization of the study, but main costs have been covered by the budget. It must be taken into account that teams and athletes taking part in the study do most of the testing at their own expense.

To complete the study, it has been calculated a budget of 78.760€. Each part of the budget and categories used for its development have been specified hereunder.

SERVICES

For controlling study protocol is being followed and for management, a management agent has been added to the budget. It has been expected for 780 hours covering 5h/week for 3 years. Paying 20€/ hour, it gives a budget of 15.600€ for Management agent salary.

It has been added 48 months' salary for Main researcher during inclusion and data collection period. Main researcher will be involved in the study, and he may not continue his work completely, that is why it has been added minimal salary for his work. This salary has been specified in 200€/month, summing up a quantity of 9.600€.

Statistical analyst will be contracted for doing the statistical analysis. It has been approximated 50 hours at 30€/h for contracting statistical analyst. Adding 1.500€ to the total budget.

Despite the study has not big impact on the subject's fitness and security, it has been added insurance expenses for 97 subjects during the study. Taking into account each subject will be in the study for maximum of 6 months, 2.000€ have been calculated for contracting minimal insurance for the athletes.

EQUIPMENT

It has been considered that doing pregnancy test every 2 weeks for 9 months maximum, could be a big charge for individuals. For that reason, buying 1000 Abbot Alere hCG Easy Test (25mIE/ml) has been decided to add in the budget, according to online price for this test and taking into account that buying big quantities price will be reduced even more than what approximated in the budget. This gives, rounding up, 20€ per unit, 20.000€ in total.

As mentioned before, Force platforms likely to be the equipment that less centres would have, because of that, it has been decided to add 20 platforms to the budget to facilitate this testing in centres that do not have this specialized equipment. Approximate price for platforms is 600€, giving a total price of 12.000€.

LOGISTICS

Apart from acquiring the equipment it will be important to have this equipment in the centres that cannot afford or do not have this equipment. Equipment will be centralized in Spain, from where it will be sent to different countries depending on demands and possibilities.

PUBLICATION AND DIVULGATION

Firstly, spreading concept has been used to determine marketing and divulgation expenses. These costs refer to divulgation for acquiring subjects for the study and article divulgation once is finished. A quantity of 2.000€ has been specified for this purpose.

The study will be sent to be published British Journal of Sports Medicine and The American Journal of Sports Medicine. In addition, Open Source international journals will also be accepted for publication. It has been settled a total budget of 7.000€ with the purpose of publication. Additional 120€ has been added for article editing and translation.

Budget	Category	Quantity	Cost/unit	Price
Statistical analyst	Services	50	30,00 €	1.500,00 €
Insurance expenses	Services	97	20,00 €	1.940,00 €
Management Agent	Services	780	20,00 €	15.600,00 €
Main Researcher Salary	Services	48	200,00 €	9.600,00 €
Article edition	Publication	1	120,00 €	120,00 €
Publication expenses	Publication	2	3.500,00 €	7.000,00 €
Spreading	Publication	1	2.000,00 €	2.000,00 €
Equiment logistics	Logistics	30	300,00 €	9.000,00 €
Force platform	Equipment	20	600,00 €	12.000,00 €
Pregnancy tests	Equipment	1000	20,00 €	20.000,00 €
TOTAL	-		*xx €*	78.760,00 €

FEASIBILITY

We believe this study to be feasible considering the following aspects.

This study will be performed multicentric, it will be carried out in different countries and different centres, which have the resources and appropriate facilities for the study. The study is designed to be multicentric to avoid making the recruitment period shorter because of reduced population. Furthermore, it will help to be more representative of general athletes, considering different ethnic groups and societies.

All the professionals who will be part of the research team, considering all the doctors that will collect data from their athletes will just be beneficiating from the data acquired and not economically. In addition, just management agent and statistical analyst will be contracted as extra personnel.

The resources needed for the study, specifically for testing athletes, are used regularly by doctors and athletes, so it will no need to have training period. Management will be easy to follow, each doctor will be able to upload their athlete's data to REDCap website to facilitate access to the researchers.

Relating to the financing of the study, cost is not especially big for the duration of the study. Taking into account how much money professional sports manage and invest on research, the feasibility of the study increases.

Inclusion of enough subjects will be one of the problems for the study, that's why importance to marketing and spreading of the study has been given. The duration of the study could be extended if inclusion period has not been enough to achieve the subjects.

To sum up, we believe that this study meets the criteria for being executed, considering the importance and specificity of the subject, the subjects required for the study and the moderated costs for a multicentric cohort study.

IMPACT

The participation of women in elite sports has been increasing in recent decades. As society development continues, reproductive planification has become increasingly challenging. Furthermore, for athletes, as optimal age for childbirth coincides with the peak performance period. Consequently, women athletes face big difficulties in making decisions regarding pregnancy.

Moreover, the lack of information related to pregnancy on elite athletes scares women from the decision taking. The absence of specific guidelines from institutions, being all the given advice general and vague, instead of recommendations according to their needs. Professionalism needs specialized considerations, general advice does not adequate to performance and reproductive planning balance.

In addition, women athletes need to face apart from personal challenges, the social attitude towards the relationship between motherhood and elite sports careers. These challenges include the fear of losing athletic status, the stigma associated with pregnancy in competitive environments, and the pressure to perform. It is vital to create a supportive framework that empowers women athletes with the knowledge and resources they need to make informed decisions.

The accomplishment of this first objective will have an impact on the management of pregnant endurance athletes, based on the recommendations that could emerge from this study. Establishing an appropriate timeline for leaving competition, ensuring both maternal security and fetal well-being while acknowledging when performance levels decline.

In the future, If the hypothesis proves right, athletes could be able to decide on their willingness to get pregnant with more information, and act accordingly to recommendations. This would help to avoid possible complications during pregnancy, particularly if high intensities are prolonged.

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ANNEXE 1: PARMED-X FOR PREGNANCY

Physical Activity Readiness
Medical Examination for
Pregnancy (2002)

PARmed-X for PREGNANCY PHYSICAL ACTIVITY READINESS MEDICAL EXAMINATION

PARmed-X for PREGNANCY is a guideline for health screening prior to participation in a prenatal fitness class or other exercise.

Healthy women with uncomplicated pregnancies can integrate physical activity into their daily living and can participate without significant risks either to themselves or to their unborn child. Postulated benefits of such programs include improved aerobic and muscular fitness, promotion of appropriate weight gain, and facilitation of labour. Regular exercise may also help to prevent gestational glucose intolerance and pregnancy-induced hypertension.

The safety of prenatal exercise programs depends on an adequate level of maternal-fetal physiological reserve. PARmed-X for PREGNANCY is a convenient checklist and prescription for use by health care providers to evaluate pregnant patients who want to enter a prenatal fitness program and for ongoing medical surveillance of exercising pregnant patients.

Instructions for use of the 4-page PARmed-X for PREGNANCY are the following:

1. The patient should fill out the section on PATIENT INFORMATION and the PRE-EXERCISE HEALTH CHECKLIST (PART 1, 2, 3, and 4 on p. 1) and give the form to the health care provider monitoring her pregnancy.
2. The health care provider should check the information provided by the patient for accuracy and fill out SECTION C on CONTRAINDICATIONS (p. 2) based on current medical information.
3. If no exercise contraindications exist, the HEALTH EVALUATION FORM (p. 3) should be completed, signed by the health care provider, and given by the patient to her prenatal fitness professional.

In addition to prudent medical care, participation in appropriate types, intensities and amounts of exercise is recommended to increase the likelihood of a beneficial pregnancy outcome. PARmed-X for PREGNANCY provides recommendations for individualized exercise prescription (p. 3) and program safety (p. 4).

NOTE: Sections A and B should be completed by the patient before the appointment with the health care provider.

A PATIENT INFORMATION

NAME _____

ADDRESS _____

TELEPHONE _____ BIRTHDATE _____ HEALTH INSURANCE No. _____

NAME OF PRENATAL FITNESS PROFESSIONAL _____ PRENATAL FITNESS PROFESSIONAL'S PHONE NUMBER _____

B PRE-EXERCISE HEALTH CHECKLIST

PART 1: GENERAL HEALTH STATUS

In the past, have you experienced (check YES or NO):

	YES	NO
1. Miscarriage in an earlier pregnancy?	❑	❑
2. Other pregnancy complications?	❑	❑
3. I have completed a PAR-Q within the last 30 days.	❑	❑

If you answered YES to question 1 or 2, please explain:

_____

Number of previous pregnancies? _____

PART 2: STATUS OF CURRENT PREGNANCY

Due Date: _____

During this pregnancy, have you experienced:

	YES	NO
1. Marked fatigue?	❑	❑
2. Bleeding from the vagina ("spotting")?	❑	❑
3. Unexplained faintness or dizziness?	❑	❑
4. Unexplained abdominal pain?	❑	❑
5. Sudden swelling of ankles, hands or face?	❑	❑
6. Persistent headaches or problems with headaches?	❑	❑
7. Swelling, pain or redness in the calf of one leg?	❑	❑
8. Absence of fetal movement after 6th month?	❑	❑
9. Failure to gain weight after 5th month?	❑	❑

If you answered YES to any of the above questions, please explain:

_____

PART 3: ACTIVITY HABITS DURING THE PAST MONTH

1. List only regular fitness/recreational activities:

_____

_____

INTENSITY	FREQUENCY (times/week) 1-2	2-4	4+	TIME (minutes/day) <20	20-40	40+
Heavy	___	___	___	___	___	___
Medium	___	___	___	___	___	___
Light	___	___	___	___	___	___

2. Does your regular occupation (job/home) activity involve:

	YES	NO
Heavy Lifting?	❑	❑
Frequent walking/stair climbing?	❑	❑
Occasional walking (>once/hr)?	❑	❑
Prolonged standing?	❑	❑
Mainly sitting?	❑	❑
Normal daily activity?	❑	❑
3. Do you currently smoke tobacco?*	❑	❑
4. Do you consume alcohol?*	❑	❑

PART 4: PHYSICAL ACTIVITY INTENTIONS

What physical activity do you intend to do?

_____

Is this a change from what you currently do? ❑ YES ❑ NO

***NOTE: PREGNANT WOMEN ARE STRONGLY ADVISED NOT TO SMOKE OR CONSUME ALCOHOL DURING PREGNANCY AND DURING LACTATION.**

Supported by: Health Canada Santé Canada

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PARmed-X for PREGNANCY

PHYSICAL ACTIVITY READINESS MEDICAL EXAMINATION

C CONTRAINDICATIONS TO EXERCISE: to be completed by your health care provider

Absolute Contraindications

Does the patient have:

	YES	NO
1. Ruptured membranes, premature labour?	❑	❑
2. Persistent second or third trimester bleeding/placenta previa?	❑	❑
3. Pregnancy-induced hypertension or pre-eclampsia?	❑	❑
4. Incompetent cervix?	❑	❑
5. Evidence of intrauterine growth restriction?	❑	❑
6. High-order pregnancy (e.g., triplets)?	❑	❑
7. Uncontrolled Type I diabetes, hypertension or thyroid disease, other serious cardiovascular, respiratory or systemic disorder?	❑	❑

Relative Contraindications

Does the patient have:

	YES	NO
1. History of spontaneous abortion or premature labour in previous pregnancies?	❑	❑
2. Mild/moderate cardiovascular or respiratory disease (e.g., chronic hypertension, asthma)?	❑	❑
3. Anemia or iron deficiency? (Hb < 100 g/L)?	❑	❑
4. Malnutrition or eating disorder (anorexia, bulimia)?	❑	❑
5. Twin pregnancy after 28th week?	❑	❑
6. Other significant medical condition?	❑	❑

Please specify: _____

NOTE: Risk may exceed benefits of regular physical activity. The decision to be physically active or not should be made with qualified medical advice.

PHYSICAL ACTIVITY RECOMMENDATION: ❑ Recommended/Approved ❑ Contraindicated

Prescription for Aerobic Activity

RATE OF PROGRESSION: The best time to progress is during the second trimester since risks and discomforts of pregnancy are lowest at that time. Aerobic exercise should be increased gradually during the second trimester from a minimum of 15 minutes per session, 3 times per week (at the appropriate target heart rate or RPE to a maximum of approximately 30 minutes per session, 4 times per week (at the appropriate target heart rate or RPE).

WARM-UP/COOL-DOWN: Aerobic activity should be preceded by a brief (10-15 min.) warm-up and followed by a short (10-15 min.) cool-down. Low intensity calesthenics, stretching and relaxation exercises should be included in the warm-up/cool-down.

PRESCRIPTION/MONITORING OF INTENSITY: The best way to prescribe and monitor exercise is by combining the heart rate and rating of perceived exertion (RPE) methods.

F	I	T	T
FREQUENCY	**INTENSITY**	**TIME**	**TYPE**
Begin at 3 times per week and progress to four times per week	Exercise within an appropriate RPE range and/or target heart rate zone	Attempt 15 minutes, even if it means reducing the intensity. Rest intervals may be helpful	Non weight-bearing or low-impact endurance exercise using large muscle groups (e.g., walking, stationary cycling, swimming, aquatic exercises, low impact aerobics)

TARGET HEART RATE ZONES

The heart rate zones shown below are appropriate for most pregnant women. Work during the lower end of the HR range at the start of a new exercise program and in late pregnancy.

Age	Heart Rate Range
< 20	140-155
20-29	135-150
30-39	130-145

RATING OF PERCEIVED EXERTION (RPE)

Check the accuracy of your heart rate target zone by comparing it to the scale below. A range of about 12-14 (somewhat hard) is appropriate for most pregnant women.

6	
7	Very, very light
8	
9	Somewhat light
10	
11	Fairly light
12	
13	Somewhat hard
14	
15	Hard
16	
17	Very hard
18	
19	Very, very hard
20	

"TALK TEST" - A final check to avoid overexertion is to use the "talk test". The exercise intensity is excessive if you cannot carry on a verbal conversation while exercising.

The original PARmed-X for PREGNANCY was developed by L.A. Wolfe, Ph.D., Queen's University. The muscular conditioning component was developed by M.F. Mottola, Ph.D., University of Western Ontario. The document has been revised based on advice from an Expert Advisory Committee of the Canadian Society for Exercise Physiology chaired by Dr. N. Gledhill, with additional input from Drs. Wolfe and Mottola, and Gregory A.L. Davies, M.D., FRCS(C) Department of Obstetrics and Gynaecology, Queen's University, 2002.

Disponible en français sous le titre «Examination medicale sur l'aptitude à l'activité physique pour les femmes enceintes (X-AAP pour les femmes enceintes)»

Additional copies of the PARmed-X for PREGNANCY, the PARmed-X and/or the PAR-Q can be downloaded from: http://www.csep.ca/forms.asp
For more information contact the:

Canadian Society for Exercise Physiology
185 Somerset St. West, Suite 202, Ottawa, Ontario CANADA K2P 0J2
tel.: 1-877-651-3755 FAX (613) 234-3565 www.csep.ca

PARmed-X for PREGNANCY

PHYSICAL ACTIVITY READINESS MEDICAL EXAMINATION

Prescription for Muscular Conditioning

It is important to condition all major muscle groups during both prenatal and postnatal periods.

WARM-UPS & COOL DOWN:
Range of Motion: neck, shoulder girdle, back, arms, hips, knees, ankles, etc.

Static Stretching: all major muscle groups

(DO NOT OVER STRETCH!)

EXAMPLES OF MUSCULAR STRENGTHENING EXERCISES

CATEGORY	PURPOSE	EXAMPLE
Upper back	Promotion of good posture	Shoulder shrugs, shoulder blade pinch
Lower back	Promotion of good posture	Modified standing opposite leg & arm lifts
Abdomen	Promotion of good posture, prevent low-back pain, prevent diastasis recti, strengthen muscles of labour	Abdominal tightening, abdominal curl-ups, head raises lying on side or standing position
Pelvic floor ("Kegels")	Promotion of good bladder control, prevention of urinary incontinence	"Wave", "elevator"
Upper body	Improve muscular support for breasts	Shoulder rotations, modified push-ups against a wall
Buttocks, lower limbs	Facilitation of weight-bearing, prevention of varicose veins	Buttocks squeeze,standing leg lifts, heel raises

PRECAUTIONS FOR MUSCULAR CONDITIONING DURING PREGNANCY

VARIABLE	EFFECTS OF PREGNANCY	EXERCISE MODIFICATIONS
Body Position	• in the supine position (lying on the back), the enlarged uterus may either decrease the flow of blood returning from the lower half of the body as it presses on a major vein (inferior vena cava) or it may decrease flow to a major artery (abdominal aorta)	• past 4 months of gestation, exercises normally done in the supine position should be altered • such exercises should be done side lying or standing
Joint Laxity	• ligaments become relaxed due to increasing hormone levels • joints may be prone to injury	• avoid rapid changes in direction and bouncing during exercises • stretching should be performed with controlled movements
Abdominal Muscles	• presence of a rippling (bulging) of connective tissue along the midline of the pregnant abdomen (diastasis recti) may be seen during abdominal exercise	• abdominal exercises are not recommended if diastasis recti develops
Posture	• increasing weight of enlarged breasts and uterus may cause a forward shift in the centre of gravity and may increase the arch in the lower back • this may also cause shoulders to slump forward	• emphasis on correct posture and neutral pelvic alignment. Neutral pelvic alignment is found by bending the knees, feet shoulder width apart, and aligning the pelvis between accentuated lordosis and the posterior pelvic tilt position.
Precautions for Resistance Exercise	• emphasis must be placed on continuous breathing throughout exercise • exhale on exertion, inhale on relaxation using high repetitions and low weights • Valsalva Manoevre (holding breath while working against a resistance) causes a change in blood pressure and therefore should be avoided • avoid exercise in supine position past 4 months gestation	

PARmed-X for Pregnancy - Health Evaluation Form

(to be completed by patient and given to the prenatal fitness professional after obtaining medical clearance to exercise)

I, _____ PLEASE PRINT (patient's name), have discussed my plans to participate in physical activity during my current pregnancy with my health care provider and I have obtained his/her approval to begin participation.

Signed: _____ Date: _____
(patient's signature)

HEALTH CARE PROVIDER'S COMMENTS:

Name of health care provider: _____

Address: _____

_____

Telephone: _____

_____

_____

_____

(health care provider's signature)

3

Advice for Active Living During Pregnancy

Pregnancy is a time when women can make beneficial changes in their health habits to protect and promote the healthy development of their unborn babies. These changes include adopting improved eating habits, abstinence from smoking and alcohol intake, and participating in regular moderate physical activity. Since all of these changes can be carried over into the postnatal period and beyond, pregnancy is a very good time to adopt healthy lifestyle habits that are permanent by integrating physical activity with enjoyable healthy eating and a positive self and body image.

Active Living:

- see your doctor before increasing your activity level during pregnancy
- exercise regularly but don't overexert
- exercise with a pregnant friend or join a prenatal exercise program
- follow FITT principles modified for pregnant women
- know safety considerations for exercise in pregnancy

Healthy Eating:

- the need for calories is higher (about 300 more per day) than before pregnancy
- follow Canada's Food Guide to Healthy Eating and choose healthy foods from the following groups: whole grain or enriched bread or cereal, fruits and vegetables, milk and milk products, meat, fish, poultry and alternatives
- drink 6-8 glasses of fluid, including water, each day
- salt intake should not be restricted
- limit caffeine intake i.e., coffee, tea, chocolate, and cola drinks
- dieting to lose weight is not recommended during pregnancy

Positive Self and Body Image:

- remember that it is normal to gain weight during pregnancy
- accept that your body shape will change during pregnancy
- enjoy your pregnancy as a unique and meaningful experience

For more detailed information and advice about pre- and postnatal exercise, you may wish to obtain a copy of a booklet entitled *Active Living During Pregnancy: Physical Activity Guidelines for Mother and Baby* © 1999. Available from the Canadian Society for Exercise Physiology, 185 Somerset St. West, Suite 202, Ottawa, Ontario Canada K2P 0J2 Tel. 1-877-651-3755 Fax: (613) 234-3565 Email: info@csep.ca (online: www.csep.ca). Cost: $11.95

For more detailed information about the safety of exercise in pregnancy you may wish to obtain a copy of the Clinical Practice Guidelines of the Society of Obstetricians and Gynaecologists of Canada and Canadian Society for Exercise Physiology entitled *Exercise in Pregnancy and Postpartum* © 2003. Available from the Society of Obstetricians and Gynaecologists of Canada online at www.sogc.org

For more detailed information about pregnancy and childbirth you may wish to obtain a copy of *Healthy Beginnings: Your Handbook for Pregnancy and Birth* © 1998. Available from the Society of Obstetricians and Gynaecologists of Canada at 1-877-519-7999 (also available online at www.sogc.org) Cost $12.95.

For more detailed information on healthy eating during pregnancy, you may wish to obtain a copy of *Nutrition for a Healthy Pregnancy: National Guidelines for the Childbearing Years* © 1999. Available from Health Canada, Minister of Public Works and Government Services, Ottawa, Ontario Canada (also available online at www.hc-sc.gc.ca).

SAFETY CONSIDERATIONS

- Avoid exercise in warm/humid environments, especially during the 1st trimester
- Avoid isometric exercise or straining while holding your breath
- Maintain adequate nutrition and hydration — drink liquids before and after exercise
- Avoid exercise while lying on your back past the 4th month of pregnancy
- Avoid activities which involve physical contact or danger of falling
- Know your limits — pregnancy is not a good time to train for athletic competition
- Know the reasons to stop exercise and consult a qualified health care provider immediately if they occur

REASONS TO STOP EXERCISE AND CONSULT YOUR HEALTH CARE PROVIDER

- Excessive shortness of breath
- Chest pain
- Painful uterine contractions (more than 6-8 per hour)
- Vaginal bleeding
- Any "gush" of fluid from vagina (suggesting premature rupture of the membranes)
- Dizziness or faintness

ANNEXE 2: PARTICIPATION INFORMATION SHEET

Participation Information Sheet

Title of the Study: Sport Performance Loss on Endurance Elite Pregnant Women: Changes in VO_{2max} and Muscular Strength

Principal Researcher:
Telmo Semperena Oyarzabal
Universidad de Girona
638626507/telmosemperena@gmail.com

With this Participation Information Sheet and the Informed consent attached, you are being invited to participate in cohort research study conducted by Girona University. This information has been created to help you understand how this study will work, benefits, risks and additional information that participating will involve. Before signing Informed Consent, reading and understanding this document is mandatory and you have the possibilities to ask for questions to the contact email before signing to participate.

Participation is completely voluntary. You could decide to participate or not participate in any point of the study without penalties. If you decide to withdrawal from the study, signing the informed consent, you give permission to use your data available to researchers.

The main objective of the study is to analyse how pregnancy affects on sport performance in elite endurance athletes, to determine the Time to Performance Loss. With the objective of concluding when competing in high intensities is not affordable and stablish recommendations to stop competing for elite athletes.

In addition, the following secondary objectives in elite endurance athletes will be studied:

- VO_{2max} evolution during pregnancy in cardiorespiratory physiological changes.
- Androgen level increment effect on muscular strength
- Maternal age effect on Time to Performance Loss
- Differences between ethnicities terms of Time to Performance Loss
- Time to Performance Loss depending on Type of Sport
- Pre-pregnancy maternal body weight effect on Time to Performance Loss
- Pre-pregnancy maternal Body Mass Index effect on Time to Performance Loss
- Gestational weight-gain and Time to Performance Loss relation
- To describe TPAL formula with obstetrical complications

Study design:

This study will be performed worldwide, with endurance elite athletes from different countries and disciplines. Reference doctors will be registering your data in the website for researchers. The study will be a follow-up of different parameters until maximum of 6 months of pregnancy.

Informed consent singed, your doctor will need to align your menstrual cycle to data collection, being the day after last menstruation day the best day for data collection. This data collection will be every 2 weeks and testing protocol will be strictly followed by your doctor and each data collection will have procedures stablished to be done.

9 months period have been stablished to facilitate you to be included in the study by achieving pregnancy. When pregnancy test turns positive you will be included in the study and data collection will continue to be every 2 weeks until you meet withdrawal criteria considered by your doctor following the protocol.

These assessments will be conducted with your sports doctor during the study and will last approximately 1 hour.

Procedures:

If you agree to participate in this study, you will be asked to:

1. Give personal information: Age, ethnicity
2. Give obstetrical information: TPAL, obstetrical problems during study
3. Give your physical information: body weight, height
4. Allow the collection of blood-analysis with hormonal information
5. Accept to do urine pregnancy-tests
6. Do incremental test to assess VO_{2max} using a treadmill
7. Do countermovement jumps to analyse muscular strength
8. Complete questionnaires about your medical and obstetrical situation

Potential Risks:

Participation in this study involves minimal risk. PARmed-X for Pregnancy questionnaire will be used every data collection day, to ensure there is not harmful obstetrical problems. If professionals see any potential risk to do the tests or competing, your study will be considered finished. To minimize risks, all assessments will be conducted by trained professionals, and you may stop the study any time if you do not feel comfortable. An insurance has been contracted in case of harm to the participants.

Benefits:

During the participation you will benefit from the continuous monitorization of your performance and fetal well-being. All your work team will need to be involved, and they will be able to use data to modify and adequate training plans. This study has as objective to help women athletes in the future, so you could contribute to create knowledge for women sport.

Confidentiality:

All data collected will be treated as confidential and stored securely in REDcap database. Identity will always be private and not accessible in publications. Data will only be accessible for the research team and your sports doctor, if data is needed for other studies, it will be anonymized to ensure privacy.

To apply to the study, you must have read this document and sign the Informed Consent attached. In addition, you will also need to fill the Personal Data Form provided by your personal doctor.

In case of any doubt contact Principal Researcher: Telmo Semperena Oyarzabal from University of Girona by email: telmosemperena@gmail,com

ANNEXE 3: INFORMED CONSENT FORM

Informed Consent Form

Title of the Study: Sport Performance Loss on Endurance Elite Pregnant Women: Changes in VO_{2max} and Muscular Strength

Principal Researcher:
Telmo Semperena Oyarzabal
Universitat de Girona
638626507/telmosemperena@gmail.com

Purpose of the Study: The main objective of the study is to analyse how pregnancy affects on sport performance in elite endurance athletes, to determine the Time to Performance Loss. With the objective of concluding, taking risks into account, when competing in high intensities is not affordable and stablish recommendations to stop competing for elite athletes.

Consent Statement:

I have read and understood the information provided in the Information sheets. I have had the opportunity to ask questions, and I agree to participate in this study. I understand that my participation is voluntary, and I give my permission to use my data for further investigation.

Participant's Name:……

Signature:

Researcher's Name: ……

Signature:

Doctor's Name: …….

Signature:

Date: …/…/….

ANNEXE 4: PERSONAL DATA FORM

Personal Data Form

Title of the Study: Sport Performance Loss on Endurance Elite Pregnant Women: Changes in VO_{2max} and Muscular Strength

Principal Researcher:
Telmo Semperena Oyarzabal
Universidad de Girona
638626507/telmosemperena@gmail.com

Personal Information

Full Name: _____

Date of Birth: _____

Medical Record number: _____

Contact Information

- Phone Number: _____
- Email Address: _____

ANNEXE 5: REFERENCE DATA COLLECTION TABLE

ATHLETE 1	x	First visit	x	Pre-pregnancy 1	x	ADD	Positive test day	x	Week 6	x	Week 8	x	ADD
Name	X	Date:	xx/xx/xxxx	Date:	xx/xx/xxxx		Date:	xx/xx/xxxx	Date:	xx/xx/xxxx	Date:	xx/xx/xxxx	
Age	X	P4	X	P4	X		P4	X	P4	X	P4	X	
Ethnicity	X	E2	X	E2	X		E2	X	E2	X	E2	X	
TPAL	xxxx	E3	X	E3	X		E3	X	E3	X	E3	X	
Typer of sport	X	SHBG	X	SHBG	X		SHBG	X	SHBG	X	SHBG	X	
Pre-pregnancy VO2max	X	Total T	X	Total T	X		Total T	X	Total T	X	Total T	X	
		Free T	X	Free T	X		Free T	X	Free T	X	Free T	X	
		DHEA-S	X	DHEA-S	X		DHEA-S	X	DHEA-S	X	DHEA-S	X	
		FAI	X	FAI	X		FAI	X	FAI	X	FAI	X	
		Body weigth	X	Body weigth	X		Body weigth	X	Body weigth	X	Body weigth	X	
		Vertical Jump	X	Vertical Jump	X		Vertical Jump	X	Vertical Jump	X	Vertical Jump	X	
		VO2max	X				VO2max	X	VO2max	X	VO2max	X	
		Pregnancy test	Negative	Pregnancy test	Negative		Pregnancy Test	POSITIVE					