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Aerobic water exercise during pregnancy for reducing use of epidural analgesia

Submission date
23/06/2017

Recruitment status
No longer recruiting

Registration date
04/09/2017

Overall study status
Completed

Last Edited
11/10/2023

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Epidural analgesia (commonly known as an epidural) is an injection placed in the back that stops that part of the body from feeling pain. It is one of the most effective methods for reducing labor pain. Although epidurals provides effective pain relief, they can lead to complications to both the mother and the baby. As an alternative to epidural analgesia, approaches to pain management that do not include medication have been examined. These include a wide variety of techniques that aim to reduce the physical sensations of pain and to prevent suffering by addressing the psychoemotional and spiritual components of care. Physical exercise during pregnancy is recommended because it provides beneficial effects without adversely affecting the fetus. Aquatic-aerobic exercise (water based exercises) has some advantages over other forms of exercise. These include reduced impact on body joints, less edema (swelling), increased diuresis (urine), reduced blood pressure, better control of body weight, less back pain and better temperature control. This study aims to demonstrate if a moderate-intensity aerobic water exercise during pregnancy could reduce epidural analgesia use and adverse events related to their use.

Who can participate?
Pregnant women aged 18 to 40 who are between 14 and 20 weeks pregnant.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive 45 minute water aerobics classes held three times weekly in an indoor pool for five months. Those in the second group receive the standard care. Participants are followed up by their midwifes and are assessed for using epidurals at birth and other birth related outcomes.

What are the possible benefits and risks of participating?
Participants may benefit from the exercise as this can reduce the mother weight gain and prevent gestational diabetes and pre-eclampsia. Also, it could help women not receive an epidural therefore reducing the side-effects of the medication. There are no direct risks with participating.

Where is the study run from?
Primary Care Management Mallorca (Spain)

When is the study starting and how long is it expected to run for?
January 2014 to December 2017 (updated 18/10/2019, previously: October 2018)

Who is funding the study?
Ministry of Economy and Competitiveness, MINECO (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PI13/02400

Study information

Scientific Title
Effectiveness and safety of moderate-intensity aerobic water exercise during pregnancy for reducing use of epidural analgesia during labor

Study objectives

Moderate-intensity aerobic water exercise during pregnancy could be an alternative to pain control during labor, reduce adverse effects such as dystocia, increase maternal satisfaction, and is likely to be readily accepted by pregnant women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Primary Care Research Committee Mallorca Ethical Committee of Clinical Research, 24/07/2014, ref: IB 2358/14 PI

Primary study design
Interventional

Study design
Multi-center parallel randomised evaluator-blinded controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Epidural analgesia side effect

Interventions
After entry details are recorded on a trial entry form, participants are randomised to either the the aquatic-aerobic exercise group or the usual antenatal care group. The 1:1 randomization is performed by a researcher not involved with treatment allocation, and are in balanced blocks of six.

Group 1: The women randomized to the water aerobics group participate in 45 min water aerobics classes held three times weekly in an indoor pool (28-30°C) for five months. This procedure is based on recommendations of the American College of Sports Medicine (36), which proposes 3-5 classes per week, a training zone of 55-65% of maximum heart rate, classes of 20-60 min duration, maximum heart rate of 140 bpm, and maintenance of body temperature below 38°C.

Aquatic exercise includes four sets of exercise were developed for the study, each set of exercise include exercises that looks at the full work of muscle groups and include breathing and relaxation techniques. All exercises are performed with coordinating breathing and includes the following:
1. Warm-up out of water (5 to 7 min)
2. Warm-up in water (5 to 10 min)
3. Moderate aquatic exercise (20 min)
4. Breathing and relaxation exercises (5 min)
5. Playful exercises (5 min)
The intervention will stop if any of the followings events appear during the trial: metrorrhagia, placenta previa, premature rupture of membranes, intrauterine growth retardation, severe anemia, or any contraindications to being physically active.

Group 2: Women in the control group receive standard antenatal care, and the customary information given by a midwife or general practitioner. They are not discouraged from exercising on their own.

Follow-up is performed by midwives who are responsible for data collection from the clinical history and from the questionnaires in all follow-up visits at gestation times of 17, 27, and 37 weeks.

Intervention Type
Behavioural

Primary outcome(s)
The incidence of epidural analgesia use during labour is determined through review of the clinical history at one month after birth

Key secondary outcome(s)
1. Morbidity (major complications, poor labor progress, intrapartum maternal fever) is determined through review of the clinical history at one month after birth
2. Pregnancy weight gain is is determined through review of the clinical history at one month after birth
3. Induction of labour is determined through review of the clinical history at one month after birth
4. Method of delivery is determined through review of the clinical history at one month after birth
5. Episiotomy or perineal tear is determined through review of the clinical history at one month after birth
6. Total labor pain is measured using a visual analogue scale (VAS) at one month after birth
7. Postnatal depression is measured using the Edinburgh postnatal depression scale (EPDS) at one month after birth
8. Health resource utilisation is determined through review of the clinical history at one month after birth
9. Quality of life is measured using the EuroQol Five Dimension questionnaire (EQ-5D) at one month after birth
10. Neonatal medical outcomes (intrapartum fetal distress, birth weight, gestational age, Apgar score, pH umbilical cord blood) is determined through review of the clinical history at one month after birth
11. Quality and quantity of sleep is measured using the Medical Outcomes Study (MOS) sleep scale at gestation times of 17, 27, and 37 weeks
12. Physical activity is measured using the International Physical Activity Questionnaire-Short Form (IPAQ-SF) at gestation times of 17, 27, and 37 weeks
13. Perceived exertion during physical activity is measured using the Modified Borg scale (MBS) at gestation times of 17, 27, and 37 weeks

Completion date
19/12/2017

Eligibility

Key inclusion criteria
1. Pregnant women who are between 14 and 20 weeks pregnant
2. Aged from 18 to 40 years-old

3. Pregnancy at low risk of complications (i.e. all women have singleton pregnancies, and none have medical, obstetric, or psychiatric problems)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Severe and poorly controlled hypertension, type 1 diabetes, or asthma
2. Hemodynamically significant heart disease, recent episode of deep venous thrombosis, hepatic insufficiency, or renal failure
3. Diagnosed mental illness or contraindications for physical activity
4. Multiparity (≥6 pregnancies), recurrent spontaneous miscarriages (≥3), incompetent cervix, increased risk of premature labor, persistent second or third trimester bleeding, uncontrolled gestational diabetes, severe isoimmunization, or planned Caesarean section
5. Severe anemia (hemoglobin < 9 mg/dL), recurrent urinary tract or vaginal infection, BMI above 35 or below 17, active and heavy smoker (>20 cigarettes/day), any drug use or abuse, chronic infectious disease (HIV, hepatitis B, hepatitis C)
6. Not being able to swim
7. Communication difficulties
8. Unwillingness to provide informed consent

Date of first enrolment
09/10/2014

Date of final enrolment
01/09/2017

Locations

Countries of recruitment
Spain

Study participating centre
Primary Care Management Mallorca (Gerencia de Atención primaria de Mallorca)
C/Reina Esclaramunda n9

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Sponsor information

Organisation
Primary Care Management Mallorca (Gerencia de Atención primaria de Mallorca)

ROR
https://ror.org/00d9y8h06

Funder(s)

Funder type
Government

Funder Name
Ministerio de Economía y Competitividad

Alternative Name(s)
Ministry of Economy and Competitiveness, MINECO, MEC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Alfonso Leiva: aleiva@ibsalut.caib.es

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/05/2021	11/10/2023	Yes	No
Protocol article	protocol	11/04/2018		Yes	No