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Prediction of hypotension caused by spinal block in caesarean section and the effect of of hypotension on foetal well-being [Predicción de la hipotensión del bloqueo espinal de las cesáreas mediante análisis de la actividad del SNA, y efectos de la profilaxis farmacológica de la hipotensión sobre el bienestar fetal]

Submission date
23/01/2012

Registration date
20/02/2012

Last Edited
03/11/2017

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Hypotension (low blood pressure) can be caused by the use of a spinal block (anaesthetic) during a caesarean section. The drug phenylephrine can be used to prevent hypotension. The aim of this study is to compare the ability of different indicators to predict hypotension in caesarian section, and to assess the effects of phenylephrine on foetal well-being.

Who can participate?
Pregnant women scheduled for caesarean section

What does the study involve?
Participants are randomly allocated to be treated with either phenylephrine or placebo (dummy drug) and ephedrine if necessary to treat the hypotension. Foetal well-being is assessed through a blood sample from the umbilical cord.

What are the possible benefits and risks of participating?
There are no known risks to participants, except for the usual side effects related to phenylephrine or caesarian section.

Where is the study run from?
Hospital Universitario Miguel Servet (Spain)

When is the study starting and how long is it expected to run for?
December 2011 to September 2013

Who is funding the study?
Aragon Institute of Health Sciences (Spain)

Who is the main contact?
Dr Augusto Navarro Hernando

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EC 10/060

Study information

Scientific Title
Prediction of hypotension caused by spinal block in caesarean section by the analysis of the activity of the autonomic nervous system, and the effects of pharmacological prophylaxis of hypotension on foetal well-being: a double-blinded prospective clinical trial

Study objectives
Prophylaxis of hypotension with phenylephrine has negative effects on the pH of umbilical cord in pregnant women who are not prone to develop hypotension, which offsets the potential positive impact of prevention on the pH of cord of patients prone to develop it. The hemodynamic stress of the decubitus supine position (supine stress test) can induce additional changes in the autonomic nervous system (ANS), which would improve the ability of heart rate variability (HRV) analysis of prediction of the hypotension. The simultaneous study of different

indicators and modes of analysis of the activity of the ANS and its variations between bed rest and supine stress will make it possible to identify the component of the spectrum of frequency variability and the indicator that is best able to predict hypotension.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Clinical Research Ethics Committee of Aragon [Comité Ético de Investigación Clínica de Aragón (CEICA)], 27/07/2011, ref: C.I.EC10/060

Study design
Prospective clinical double-blinded trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Caesarean section and hypotension after spinal block

Interventions
For the anaesthetic technique and management, the interventions included will be crystalloid preload with Ringer Lactate 1000 ml, puncture in site position in L3-4 or L2-3 with Withacre G25 or G27 needle, block with Bupivacaine 0.5% hyperbaric (10 mg in height <155cm, 11mg in height 155-165 cm, 12 mg in >165 cm) with 0.15 mg of morphic chlorure conservant free addition. Supine position with 45º left tilt. Maintenance of the venous with a Ringer Lactated infusion at 15 ml/kr-1min-1.

If the patient is assigned to treatment group, they will receive a parallel infusion of phenylephrine through an infusion bomb at 1 mlkg-1min-1 for the hypotension prophylaxis, and if the patient is assigned to control group will only receive a placebo infusion. The hypotension treatment will consist of an ephedrine intravenous bolus correction in both groups if necessary, with an initial 5 mg dose, and adding additional bolus if the hypotension does not stop.

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Phenylephrine

Primary outcome measure
The first part of the trial will study different indicators of the ANS (autonomic nervous system) activity and their arterial hypotension prediction capacity related to the caesarean intervention spinal anaesthesia. The ANS activity will be measured through HRV, PRV and Pulse Transit Time Variability (PTTV) and a digital register of the ECG curve

Secondary outcome measures
The second part of the trial is the study of the hypotension prophylaxis with phenylephrine effect on foetal well-being. This will be measured through an arterial and venous blood sample from the umbilical cord to determinate gases, acid-base balance and lactic acid
Other measurements will be done, a register and evaluation of the maternal total antioxidant system (TAS), TAM, TAD, FC and oxygen saturation (Sat O2) at baseline and at 5 and 20 minutes of the epinephrine bolus infusion, the number of epinephrine bolus, dose and administration time and the times of epinephrine bolus initiation, uterine incision and foetal extraction, nausea and vomiting (adverse effects)

Overall study start date
13/12/2011

Completion date
01/09/2013

Eligibility

Key inclusion criteria
1. Pregnant women scheduled for caesarean section in first turn on the surgical part
2. Informed consent to participate in the trial asked in the preanaesthetic consultation

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
80

Key exclusion criteria
1. Presence of uterine dynamics
2. Multiple pregnancies
3. Maternal pathology related or not with the gestation
4. Suspicion of foetal pathology

Date of first enrolment
13/12/2011

Date of final enrolment
01/09/2013

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitario Miguel Servet
Zaragoza
Spain
50009

Sponsor information

Organisation
Aragon Institute of Health Sciences (Instituto Aragonés de Ciencias de la Salud) (Spain)

Sponsor details
Avenida Gómez Laguna 25
Planta 11
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Spain
50009

Sponsor type
Research organisation

Website
http://www.ics.aragon.es/

ROR
https://ror.org/05p0enq35

Funder(s)

Funder type
Research organisation

Funder Name
Aragon Institute of Health Sciences (Instituto Aragonés de Ciencias de la Salud) (Spain)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration