

# 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]

<b>Submission date</b> 23/01/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/02/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 03/11/2017	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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**  
Dr Augusto Navarro Hernando

**Contact details**  
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50009

## 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 45° 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 O<sub>2</sub>) 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**

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Planta 11

Zaragoza

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