

# Ropivacaine for pain management in patients who undergo Caesarean section

<b>Submission date</b> 01/05/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/05/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/05/2022	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

A Caesarean section is surgery to deliver a baby. The baby is taken out through the mother's abdomen. Some Caesarean sections are planned, but many are done when unexpected problems happen during delivery.

Pain following a Caesarean section has a negative influence on the child and mother. The main aim of this study is to analyse the postoperative pain after a dosage of preperitoneal ropivacaine.

### Who can participate?

Women between the age of 18 and 40 years with full-term pregnancy, undergoing a planned or elective Caesarean section.

### What does the study involve?

Patients were randomly allocated to two groups: group A would receive general analgesics (ketorolac) and ropivacaine while group B would only receive general analgesics. Pain is measured using the visual analogue scale (VAS).

### What are the possible benefits and risks of participating?

The benefits of this trial include reduction of postoperative pain, a reduction of complications due to pain, reduction of hospital stay and a reduction in hospitalization costs. The possible risks include those caused by the ropivacaine drug-like hematomas, nausea, vomiting and ecchymosis; those due to the intravenous infiltration of ropivacaine like tinnitus, metallic taste, paresthesia, vertigo, anxiety, nystagmus, hallucinations, convulsions, apnea and coma, all of which were prevented, treated and registered.

### Where is the study run from?

The Division of Obstetrics, High Specialty Medical Unit of the Hospital of Gynecology and Pediatrics # 48, part of the Mexican Social Security Institute (Mexico)

### When is the study starting and how long is it expected to run for?

August 2018 to February 2020

Who's funding the study?  
Investigator initiated and funded

Who's the main contact?  
Gloria Patricia Sosa Bustamante, patriciasosab@hotmail.com

## Contact information

### Type(s)

Public

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

Nil known

## Study information

### Scientific Title

Preperitoneal ropivacaine in the management of postoperative pain in post-Caesarean section patients

### Study objectives

Preperitoneal ropivacaine in the postoperative management is effective against the pain in post-cesarean section patients,

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 29/08/2018, Ethics Committee for Health Research (Comité de Ética para la Investigación en Salud, Avenue Paseo de los Insurgentes, col. Los Paraísos, 37328 Leon Gto, Mexico; +52 477 717 4800 ext.31800; comision.etica@imss.gob.mx), ref: 10028

### Study design

Randomized double-blind controlled clinical 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 contact details to request a participant information sheet

## **Health condition(s) or problem(s) studied**

Post-operative pain management in patients who undergo cesarean section

## **Interventions**

The patients were randomly assigned, by simple random sampling, into two groups (A and B), in accordance with a table of random numbers. Preperitoneal ropivacaine was administered in group A, while group B (control) did not receive this. In the operating room, they were administered regional anesthesia through L2 - L3 epidural block, with 2% lidocaine with epinephrine, at a dose of 4 mg per kg of body weight, with a latency time of 10 to 15 minutes. The cesarean section was performed with the conventional technique, with a mid-infraumbilical incision in the skin and a Kerr-type incision in the uterus, the hysterorrhaphy was sutured in three planes. Before proceeding with the closure of the surgical wound, patients in group A received preperitoneal ropivacaine. The perincisional parietal peritoneum (subfascial) was located and taken with four Kelly forceps, a 22 G needle was inserted, up to 2 cm deep over the edge of the peritoneum, in the preperitoneal space and at an angle of 45 °, 30 ml were infiltrated of ropivacaine 0.75%, corresponding to 225 mg total (7.5 mg/ml bottle). In group B patients, the conventional cesarean section was performed in the same way as previously explained, but without the application of ropivacaine. No substance was administered as a placebo.

## **Intervention Type**

Drug

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

Ropivacaine

## **Primary outcome measure**

Pain was measured using the VAS scale at the end of the surgery (baseline), 2, 6, 12, 18 and 24 hours after surgery.

## **Secondary outcome measures**

1. Use of rescue doses was measured using the VAS scale at the end of the surgery (baseline), 2, 6, 12, 18 and 24 hours after surgery.
2. Days of hospital stay were measured using the medical record over a 10 day period after the surgery
3. Presence of adverse events was measured using medical examination over a 10 day period after the surgery

## **Overall study start date**

29/08/2018

**Completion date**

22/02/2020

## **Eligibility**

**Key inclusion criteria**

1. Women from 18 to 40 years of age
2. Term pregnancy
3. Undergoing programmed or elective cesarean section

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

2 clusters with 41 participants each

**Total final enrolment**

81

**Key exclusion criteria**

1. Chronic diseases
2. Placental disorders
3. Infections
4. Aallergies to anesthetics
5. Contraindication to regional anesthesia
6. Obstetric emergency
7. History of drug abuse
8. Inability to understand the visual analog scale

**Date of first enrolment**

17/10/2018

**Date of final enrolment**

20/12/2019

## **Locations**

**Countries of recruitment**

Mexico

**Study participating centre**

**High Specialty Medical Unit. Hospital of Gynecology and Pediatrics #48. Mexican Social Security Institute.**

Avenue Paseo de los Insurgentes (no #) col. Los Paraísos

León

Mexico

37328

## **Sponsor information**

**Organisation**

Mexican Social Security Institute

**Sponsor details**

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**Sponsor type**

Government

**Website**

<http://www.imss.gob.mx/>

**ROR**

<https://ror.org/03xddgg98>

## **Funder(s)**

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

## Intention to publish date

20/05/2022

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Gloria Patricia Sosa Bustamante with the emails patriciasosab@hotmail.com and gloria.sosa@imss.gob.mx.

The type of data that will be shared only includes clinical variables (acronyms for the names, age, BMI, births, past cesarean sections and gestational age).

The individual participant data will be available upon request and for an undetermined amount of time.

The data will not be shared with anyone unless the platform ISRCTN requests the data through the emails that were shared earlier to corroborate the existence of the IPD.

Anonymisation will be kept by using acronyms of the participants' names.

As of the ethical restrictions, on the informed consent, the researchers indicated to the participants that their personal data would be protected as well as that clinical variables would only be used for the analysis of the data and publication on a scientific journal.

## IPD sharing plan summary

Stored in non-publicly available repository, Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other unpublished results</a>			19/05/2022	No	No
<a href="#">Participant information sheet</a>			19/05/2022	No	Yes