ISRCTN15849443 https://doi.org/10.1186/ISRCTN15849443

Ropivacaine for pain management in patients who undergo Caesarean section

Submission date
01/05/2022

Recruitment status
No longer recruiting

Registration date
24/05/2022

Overall study status
Completed

Last Edited
24/05/2022

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 ropivicaine 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

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
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Sponsor information

Organisation
Mexican Social Security Institute

ROR
https://ror.org/03xddgg98

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

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 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 dara 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?
Other unpublished results			19/05/2022	No	No
Participant information sheet			19/05/2022	No	Yes