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Prevention of nausea and vomiting comparing ondansetron and dexamethasone versus placebo in cesarean section under regional anesthesia

Submission date
07/07/2016

Recruitment status
No longer recruiting

Registration date
17/07/2016

Overall study status
Completed

Last Edited
09/08/2019

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
A caesarean is an operation used to deliver a baby, which can be planned or used as an emergency procedure, when a natural birth is not an option. It involves making a cut in the mother's tummy (abdomen) wall and the womb, through which the baby is taken through. A caesarean can be a planned (elective) procedure, if the need for it becomes apparent during pregnancy or if the mother asks for it. The procedure is usually performed when the woman is awake under regional anaesthtic (numbing of the lower half of the body). This often involves an injection of an anaesthetic (numbing agent) and pain killer (such as morphine) mixture into the spine in the lower back. The use of intrathecal (injection into the spine) morphine is an effective method for pain relief in postoperative cesarean section, but has undesirable side effects such as nausea, vomiting and itching. The aim of this study is to test two drugs to find out if they can reduce nausea, vomiting and itching after receiving intrathecal morphine: dexamethasone (which prevents inflammation (swelling)) and ondansetron (which blocks the chemicals in the body which can trigger nausea and vomiting).

Who can participate?
Pregnant women aged between 18 and 40 who are scheduled for an elective caesarean section with spinal pain relief.

What does the study involve?
Participants are randomly allocated to one of three groups, who each receive a different treatment through a drip when they have their pain killer injection into the spine before surgery. Those in the first group receive 4mg of ondansetron in 5ml normal saline (salt water). Those in the second group receive 4mg of dexamethasone in 5ml normal saline. Those in the third group receive 5ml normal saline only with no drugs added. During surgery and then two, six and 24 hours afterwards, participants in all groups are asked to rate their nausea and any vomiting is recorded. The risk of nausea and vomiting is then calculated for each group. Participants are also asked whether their skin feels itchy so that the risk of itchy skin can be calculated.

What are the possible benefits and risks of participating?
Participants benefit from having more intensive monitoring and timely management of vomiting or nausea after their surgery. There are no notable risks involved with participating in this study.

Where is the study run from?
Clinica materno infantil San Luis (Columbia)

When is the study starting and how long is it expected to run for?
February 2014 to September 2016

Who is funding the study?
Industrial University of Santander (Columbia)

Who is the main contact?
Dr Rodolfo Parra Güiza

Contact information

Type(s)
Public

Contact name
Dr Rodolfo Parra Güiza

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
.

Study information

Scientific Title

Prophylaxis of postoperative nausea and vomiting in cesarean section under spinal anesthesia with intrathecal morphine: controlled clinical trial comparing ondansetron vs placebo vs dexamethasone

Study objectives
Dexamethasone and Ondansetron are better than placebo for the prevention of nausea and vomiting in patients undergoing cesarean section under regional anesthesia and intrathecal morphine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional review board of the Clínica materno infantil San Luis (Colombia), 18/01/2014

Study design
Single-centre randomized placebo-controlled triple-blind trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
1. Postoperative nausea and vomiting
2. Pruritus

Interventions
300 patients are randomized to one of three groups in a 1:1:1 ratio.

Ondansetron group: Participant receive 4 mg of ondansetron in 5 mL normal saline
Dexamethasone group: Participant receive 4 mg of dexamethasone in 5 mL normal saline
Placebo group: Participant receive 5 mL normal saline

In all groups, study drugs are administered at the time of lumbar puncture for the administration of the anesthetic-analgesic mixture (9 mg of bupivacaine + 25 micrograms fentanyl 100 micrograms of morphine) by the anesthesiologist responsible for the case.

Patients are evaluated intraoperatively, and then 2, 6 and 24 hours after intrathecal morphine. They are questioned about nausea and vomiting, need for rescue antiemetics, itching and pain

using a numeric scale to indicate the severity of these symptoms (nausea, itching and pain). If patients have vomiting or severe nausea (numerical rating scale >7) postoperatively, they receive 4 mg of dexamethasone and 4 mg of ondansetron as antiemetic rescue therapy.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Ondansetron, Dexamethasone, Normal saline

Primary outcome measure
1. Incidence of nausea and vomiting is measured using a numerical rating scale (NRS) at 2, 6 and 24 hours after intrathecal morphine
2. Relative risk of nausea and vomiting by dividing the percentage cases of nausea and vomiting in the control group by the percentage cases in each of the intervention groups
3. Number needed to treat for nausea and vomiting is measured by the inverse of the Absolute Risk reduction (ARR) (% of cases of nausea on placebo group - % of cases of nausea on ondansetron or dexamethasone group) intraoperatively, at 2, 6 and 24 hours after intrathecal morphine

Secondary outcome measures
1. Incidence of pruritus is measured using a numerical rating scale (NRS) intraoperatively, at 2, 6 and 24 hours after intrathecal morphine
2. Relative risk of pruritus by dividing the percentage cases of pruritus in the control group by the percentage cases in each of the intervention groups

Overall study start date
22/02/2014

Completion date
01/09/2016

Eligibility

Key inclusion criteria
1. Pregnant patients scheduled for elective caesarean
2. Age between 18 - 40 years old
3. Spinal (Subarachnoid) anesthesia with intrathecal morphine
4. ASA Physical status 1-2

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Female

Target number of participants
300

Total final enrolment
300

Key exclusion criteria
1. Preeclampsia
2. Eclampsia
3. Kidney and/or liver failure
4. Known allergy to ondansetron or dexamethasone
5. Heart disease
6. Vertigo
7. Hyperemesis gravidarum
8. Nausea and vomiting or itching
9. Previous cesarean section
10. 5 HT3 antagonists or corticoids allergy
11. Gestational diabetes
12. Immunosuppression
13. Congenital long QT syndrome
14. Neurological or psychiatric illness that would prevent obtaining consent for the study
Emergency Caesarean
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Date of first enrolment
17/09/2015

Date of final enrolment
11/12/2015

Locations

Countries of recruitment
Colombia

Study participating centre
Clinica materno infantil San Luis
Cra. 26 #48-56
Bucaramanga
Colombia
680003

Sponsor information

Organisation
Industrial University of Santander (Universidad Industrial de Santander)

Sponsor details
Cra. 30 #34-54
Bucaramanga
Colombia
680002

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00xc1d948

Funder(s)

Funder type
University/education

Funder Name
Industrial University of Santander (Universidad Industrial de Santander)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/09/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results [in Spanish]	30/04/2018	09/08/2019	Yes	No