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The analgesic efficacy of a low dose of bupivacaine plus fentanyl versus a conventional dose of bupivacaine plus fentanyl for subarachnoid anaesthesia during caesarean section

Submission date	Recruitment status	[ ] Prospectively registered
12/02/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/02/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/02/2011	Pregnancy and Childbirth	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

U1111-1119-4404

Study information

Scientific Title
The analgesic efficacy of a low dose of bupivacaine plus fentanyl versus a conventional dose of bupivacaine plus fentanyl for subarachnoid anaesthesia during caesarean section: A controlled clinical trial

Study objectives
The efficacy of postoperative analgesia with low dose is better (in duration, sensory level and satisfaction) than presented with 12.5 mg hyperbaric bupivacaine plus fentanyl 25 mcg in regional subarachnoid technique for caesarean procedures in patients of american society of anaesthesiologists (ASA) II Neiva hospital.

Intraoperative maternal side effects of hyperbaric bupivacaine 7.5 mg plus fentanyl 25 mcg are less than 12.5 mg hyperbaric bupivacaine plus fentanyl 25 mcg in regional subarachnoid technique for caesarean section procedures in ASA II patients at the hospital of Neiva.

This trial was designed to compare low doses of hyperbaric bupivacaine with fentanyl versus conventional doses in several respects: haemodynamic stability, pain, intra operative comfort and satisfaction with the use of different concentrations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bioethics committee of the University Hospital of Neiva approved on May 14th 2010, ref no:026

Study design
Prospective single-centre randomised double-blind study

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Caesarean section-spinal anaesthesia

Interventions
The patients that met the inclusion criteria were assigned to one of the two comparison groups by a random number table:
1. Group 1 received 7.5 mg of hyperbaric bupivacaine 0.5% plus 25 µg of fentanyl
2. Group 2 received 12.5 mg of hyperbaric bupivacaine 0.5% plus 25 µg of fentanyl

For both groups, the total solution volume was 3 ml. Group 1 was supplemented with 1 ml of saline.

The drug was prepared by a chemical pharmacy and a second person was designated to the group to make the markings on the syringes. Neither the anaesthesiologist who performed the procedure and readied the syringe nor the research team knew the drug supplied. On admission to the surgical ward, patients were monitored with non-invasive blood pressure (NIBP), electrocardiogram (ECG) at D II derivation, heart rate measurements, pulse oximetry, and respiratory rate measurements and supplemental oxygen was administered via a nasal cannula at 2 liter per minute.

All patients received load of 7 ml / kg of 0.9% normal saline solution (SSN) or Ringers lactate in 10-15 minutes. Patients were placed in a sitting position and a 26 G Quincke needle was inserted at the L3-4 interspace by a medial or paramedial approach. Asepsis was ensured by performing antisepsis at the lumbar region. Clear cerebrospinal fluid was injected with an anesthetic solution at a rate of 1 ml/25 s bubbling. After the injection, the position of the needle was confirmed by aspiration of 0.5 ml of CSF and re-injected. The patient was immediately accommodated in a supine neutral position by passing the uterus 15 degrees to the left using a wedge. Maintenance was performed with 0.9% SSN or Ringer's lactate at 10 ml / kg / h. If the mean arterial pressure decreased by more than 20% compared to baseline levels or systolic blood pressure reached levels below 90 mmHg, ephedrine was administered by IV at a dose of 5-10 mg. If this dose failed to anesthetise, etilefrine or phenylephrine was administered at a dose of 50-100 µg. If the heart rate reached levels below 50 beats per minute, then the patient was given atropine at a dose of 0.01 to 0.02 mg/k.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
bupivacaine, fentanyl

Primary outcome measure
1. The maternal side effects
2. Intraoperative pain
3. Onset time for motor and sensory block, motor block level, maximum level of sensory block, patient and obstetrician satisfaction. The assessment of sensory block was made by prick and thermal sensitivity, while motor block was evaluated using the Bromage scale
3.1. I-patient moves only the legs,
3.2. II- Patient moves only the feet
3.3. III- The knees flex
3.4 IV-patient raises and extends the legs .
This evaluation was performed at 5, 10, and 15 minutes with the medicine cord.

4. For transitional analgesia, 50 mg / k doses of dipyrone were administered intraoperatively. If anesthetic effects were not properly observed (absence of sensory and motor block), the procedure was repeated with the same dose. In cases of inadequate anesthesia (presence of surgical pain after 20 minutes) or cases in which the patients discomfort or inconvenience was related to manipulation of the uterus, the patient was administered a fentanyl bolus of 50 µg then two bowls by IV. If full pain management was not achieved, the general anesthetic technique was used.

Secondary outcome measures
1. Patient and obstetrician satisfactions were defined as satisfied, moderately satisfied, very satisfied or unsatisfied
2. Postoperative pain was evaluated at two and six hours after operation by a verbal numerical scale (0-10, with 0 indicating no pain and 10 indicating excruciating pain). If the patient indicated a number greater than 5, a 4 mg / k dose of morphine was added via IV.

Overall study start date
01/07/2010

Completion date
31/10/2010

Eligibility

Key inclusion criteria
1. Pregnant patients over 18 years with an indication of caesarean section
2. ASA II patient

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
65

Key exclusion criteria
1. Patient who refused to enter the study
2. Patients with known hypersensitivity to any of the anesthetic agents used in the study
3. Patients with contraindication to spinal block
4. Procedures lasting more than an hour
5. Patients with multiple pregnancy or premature birth
6. Patients receiving non-steroidal anti-inflammatory drugs (NSAIDs) and / or opioids intravenous (IV) in the last 4 hours

Date of first enrolment
01/07/2010

Date of final enrolment
31/10/2010

Locations

Countries of recruitment
Colombia

Study participating centre
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03c81c376

Funder(s)

Funder type
Other

Funder Name

Investigator initiated and funded (Colombia)

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