

# 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

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<b>Registration date</b> 28/02/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/02/2011	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**Protocol serial number**  
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

### **Primary study design**

Interventional

### **Study design**

Prospective single-centre randomised double-blind study

### **Study type(s)**

Treatment

### **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(s)**

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 dipyron 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.

### **Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**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**  
Neiva City University Hospital (Colombia)

**ROR**  
<https://ror.org/03c81c376>

## **Funder(s)**

**Funder type**  
Other

**Funder Name**  
Investigator initiated and funded (Colombia)

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration