

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Comparison of two different doses of 0.5 % bupivacaine added to sufentanil intrathecal on sensory block and incidence of hypotension in cesarean section under spinal anesthesia.

#### Protocol summary

##### Summary

The aim of this study is to determine an effective dose of local anesthetic in spinal block for cesarean section accompanied with proper sensory block and decrease of hypotension incidence. This study is a randomized, double blind clinical trial (phase 4), that 100 healthy cases between 18 to 45 years old with term pregnancy that are candidate for cesarean section under spinal anesthesia will be divided in two groups named A & B in 4 random block. Exclusion criteria will include patients with multiple pregnancy; emergency cesarean delivery; preeclampsia and eclampsia; cardiovascular; pulmonary; thyroid diseases; hypertension and contraindications of spinal anesthesia. Blood pressure; heart rate and arterial oxygen saturation (SPO2) will be recorded for all patients after receiving 10 ml / kg Ringer. Patients will be anesthetized by spinal block with 25 G needle. In first group; 8 mg of bupivacaine 0.5% added to 2.5 micrograms of Sufentanil and in second group; 10 mg of bupivacaine 0.5% added to 2.5 micrograms of Sufentanil with a total volume of 2.5 ml in similar syringes will be injected into the subarachnoid space. Then vital signs in 1,2,3,4,5,10,15,20,30,40,50 , 60 minutes after spinal anesthesia will be measured and recorded . Sensory and motor block of patients will be recorded before surgery and in recovery. Pain severity will be recorded by VAS of pain in skin incision, neonate delivery, skin closure and recovery times.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017030510841N7**  
Registration date: **2017-06-02, 1396/03/12**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-06-02, 1396/03/12

##### Registrant information

###### Name

Nahid Manouchehrian

###### Name of organization / entity

Hamedan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1827 7012

###### Email address

manouchehrian@umsha.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Hamadan University of Medical Sciences , Vice chancellor of research

##### Expected recruitment start date

2017-01-20, 1395/11/01

##### Expected recruitment end date

2017-05-22, 1396/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of two different doses of 0.5 % bupivacaine added to sufentanil intrathecal on sensory block and incidence of hypotension in cesarean section under spinal anesthesia.

**Public title**

Determination of effective local anesthetic dose in spinal anesthesia

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: 18-45 years old patients with ASA class 1&2; Term pregnancy(Gestational age 36-40 week) and candidate for cesarean section under spinal anesthesia.

Exclusion criteria: High risk and Multiple pregnancy; Emergency cesarean section; Pre-eclampsia and eclampsia; Cardio vascular disorders; Respiratory disorders; Thyroid diseases; Hypertension and spinal anesthesia contraindications( Patient refusal; Increasing of intracranial pressure; Regional infection; Coagulopathy; Anemia and hypovolemia).

**Age**

From **18 years** old to **45 years** old

**Gender**

Female

**Phase**

4

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

In this study patients are divided in two groups A & B in 4 random block .

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan university of medical sciences

**Street address**

Fahmide Street

**City**

Hamadan

**Postal code**

6517838678

**Approval date**

2017-04-08, 1396/01/19

**Ethics committee reference number**

IR.UMSHA.REC.1396.45

**Health conditions studied****1****Description of health condition studied**

Hypotension & sensory block level during spinal anesthesia in c/s

**ICD-10 code**

074.6

**ICD-10 code description**

Other complications of spinal and epidural anaesthesia during labour and delivery

**Primary outcomes****1****Description**

consumption of aropin

**Timepoint**

end of surgery and recovery

**Method of measurement**

mg and by observation & calculation

**2****Description**

consumption of ephedrine

**Timepoint**

end of surgery and recovery

**Method of measurement**

mg and by observation & calculation

**3****Description**

SPO2

**Timepoint**

1,2,3,4,5,10,15,20,30,40,50,60 minutes after spinal anesthesia

**Method of measurement**

Percent and by pulse oxymetry

**4****Description**

sensory block level

**Timepoint**

before surgery and recovery

**Method of measurement**

determination of sensory level by needle (pinprick)

**5****Description**

motor block level

**Timepoint**

before surgery and recovery

**Method of measurement**

bromage score

## 6

### **Description**

systolic and diastolic blood pressure

### **Timepoint**

1,2,3,4,5,10,15,20,30,40,50,60 minutes after spinal anesthesia

### **Method of measurement**

mm Hg & by automatic non invasive blood pressure

## 7

### **Description**

Mean arterial pressure

### **Timepoint**

1,2,3,4,5,10,15,20,30,40,50,60 minutes after spinal anesthesia

### **Method of measurement**

mm Hg & by automatic non invasive blood pressure

## 8

### **Description**

Heart Rate

### **Timepoint**

1,2,3,4,5,10,15,20,30,40,50,60 minutes after spinal anesthesia

### **Method of measurement**

Beat per minute and by ECG monitoring

## 9

### **Description**

new born Apgar

### **Timepoint**

1&5 minutes after delivery

### **Method of measurement**

Apgar Score

## 10

### **Description**

determination of pain

### **Timepoint**

skin incision, neonate delivery, skin closure, recovery

### **Method of measurement**

visual analgesic scale (10 cm ruler)

## **Secondary outcomes**

## 1

### **Description**

pruritis

### **Timepoint**

during surgery

### **Method of measurement**

Observation & visual scale

## 2

### **Description**

nausea & vomiting

## **Timepoint**

during surgery and in recovery

## **Method of measurement**

Observation and questioning the patient

## **Intervention groups**

## 1

### **Description**

In intervention group: After entering patients into operating room they receive 10 ml/kg ringer solution through a 18 G intravenous catheter. They will be anesthetized with spinal block in a sitting position by an anesthesiologist with a needle (25 G). In the first group, 8 mg of bupivacaine 0.5% with 2.5 micrograms of sufentanil with a total volume of 2.5 ml will be injected in the subarachnoid space.

### **Category**

Prevention

## 2

### **Description**

In control group: After entering patients into operating room they receive 10 ml/kg ringer solution through a 18 G intravenous catheter. They will be anesthetized with spinal block in a sitting position by an anesthesiologist with a needle (25 G). In the second group, 10 mg of bupivacaine 0.5% with 2.5 micrograms of sufentanil with a total volume of 2.5 ml will be injected in the subarachnoid space.

### **Category**

Prevention

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Fatemieh Hospital

#### **Full name of responsible person**

Nahid Manouchehrian

#### **Street address**

Pasdaran Street

#### **City**

Hamadan

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Hamadan University of Medical Science, vice chancellor of research

#### **Full name of responsible person**

Dr. Saeed Bashirian

#### **Street address**

Fahmide Street

#### **City**

Hamadan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hamadan University of Medical Science, vice chancellor of research

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

empty

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Hamadan University of Medical Science-Fatemie Hospital

**Full name of responsible person**

Nahid Manouchehrian

**Position**

Associated professor of anesthesia Department-Special Board of Anesthesia

**Other areas of specialty/work**

**Street address**

Pasdaran Street

**City**

Hamadan

**Postal code**

6517789971

**Phone**

+98 81 3827 7012

**Fax**

+98 81 3828 3939

**Email**

manuchehriann@gmail.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Hamadan University of Medical Sciences-Fatemie Hospital

**Full name of responsible person**

Nahid Manouchehrian

**Position**

Associated professor of Anesthesia Department-Special Board of Anesthesia

**Other areas of specialty/work**

**Street address**

Pasdaran Street

**City**

Hamadan

**Postal code**

65177-89971

**Phone**

+98 81 3827 7012

**Fax**

+98 81 3821 0171

**Email**

manuchehriann@gmail.com  
manouchehrian@umsha.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Hamadan University of Medical Sciences-Fatemie Hospital

**Full name of responsible person**

Nahid Manouchehrian

**Position**

Associated professor of Anesthesia Department-Special Board of Anesthesia

**Other areas of specialty/work**

**Street address**

Pasdaran Street

**City**

Hamadan

**Postal code**

65177-89971

**Phone**

+98 138277012

**Fax**

+98 81 3821 0171

**Email**

manuchehriann@gmail.com  
manouchehrian@umsha.ac.ir

**Web page address**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

empty

**Study Protocol**

empty

**Statistical Analysis Plan**

empty

**Informed Consent Form**

empty

**Clinical Study Report**

empty

**Analytic Code**

empty

**Data Dictionary**

empty