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 Manuchehrian
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 chanceller 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-eclampcia and eclampcia; Cardio vascular disorders; Respiratory disoeders; 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 presure
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 sergury 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.commanouchehrian@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.commanouchehrian@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