

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of unilateral spinal anesthesia and epidural anesthesia for unilateral below T10 sensory level surgeries

Protocol summary

Summary

The present study was designed to comparison of hemodynamic changes in unilateral spinal and epidural anesthesia in patients undergoing surgery below T10 sensory level. 120 patients aged between 18 to 70 years, with candidate of surgery below T10 sensory level that signed the written informed consent will be selected randomly divided into two group which receiving unilateral spinal and epidural anesthesia, separately. All patients who suffering from kidney, liver, cardiovascular diseases, coagulopathy, skin infection at injection site, sever hypervolemia, hypersensitivity to local anesthesia drug and sever hypotension will be excluded. The patients will be randomly allocated into one of two groups. In group one, patients receive unilateral spinal anesthesia. after subarachnoid injection in sitting position, patients are going to supine positions immediately and then Tilt to the surgical site (45 degrees). L2-L3 and L3-L4 space spinal Quinke G25 puncture spinal has done Approach midline. Then 3 cc Marcaine 0/5% is injected. In group two, patients receive epidural anesthesia. In Sitting position the epidural catheter is threaded the Tuohy G17 needle through L2-L3 or L3-L4 space. Loss of resistance techniques used to find the space. Epidural test dose of lidocaine ml 3 2% + μ / ml 5 epinephrine injected into the epidural space to ensure the integrity. After injected 15ml Marcaine 0/5%, the patient is given into supine position. Systolic and diastolic blood pressure, heart rate, saturated arterial oxygen, will be measured at the beginning and during the surgery and incidence of headache, backache, nasua and vomiting will be determined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020819771N2**

Registration date: **2016-07-27, 1395/05/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-27, 1395/05/06

Registrant information

Name

Aroona Chabra

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3345 3084

Email address

aroonachabra2@yahoo.com

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of unilateral spinal anesthesia and epidural anesthesia for unilateral below T10 sensory level surgeries

Public title

Comparison of unilateral spinal anesthesia and epidural anesthesia

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: patient satisfactory; Elective unilateral spinal anesthesia or epidural anesthesia for unilateral below T10 sensory level surgeries; ASA

Class 1-2 (American Society of Anesthesiologists)

Exclusion criteria: Patient refusal; Patient disability to remain calm in needle puncture; Increasing intra cranial pressure; Skin infection; Hypervolemia; Sensitive to local anesthesia drugs; Peripheral neuropathy; Nervous disorders; Severe hypotension; Cardiovascular disease; Hepatic disorders; Kidney failure

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences

Street address

Mazandaran-Sari- Moallem Square

City

Sari

Postal code

Approval date

2015-03-04, 1393/12/13

Ethics committee reference number

118

Health conditions studied

1

Description of health condition studied

Spinal and epidural anesthesia

ICD-10 code

T88

ICD-10 code description

Other complications of surgical and medical care, not elsewhere classified

Primary outcomes

1

Description

blood pressure

Timepoint

12 month

Method of measurement

manometer

2

Description

heart rate

Timepoint

12 month

Method of measurement

monitoring system

3

Description

arterial saturation oxygen

Timepoint

12 month

Method of measurement

monitoring system

4

Description

nausea and vomiting

Timepoint

12 month

Method of measurement

checklist

5

Description

backage

Timepoint

12 month

Method of measurement

checklist

6

Description

headache

Timepoint

12 month

Method of measurement

checklist

Secondary outcomes

1

Description

headache

Timepoint

12month

Method of measurement

checklist

2

Description

hypotension

Timepoint

12month

Method of measurement

manometer

3

Description

backache

Timepoint

12month

Method of measurement

checklist

4

Description

nausea and vomiting

Timepoint

12month

Method of measurement

checklist

5

Description

heart rate

Timepoint

12month

Method of measurement

manometer

Intervention groups

1

Description

Group A: After subarachnoid injection in Sitting position, patients are going to supine positions immediately and then Tilt to the surgical site (45 degrees). L2-L3 and L3-L4 space spinal Quinke G25 puncture spinal has done Approach midline. Then 3 cc Marcaine 0/5% is injected.

Category

Treatment - Other

2

Description

Group B: Patients receive epidural anesthesia. In Sitting position the epidural catheter is threaded the Tuohy G17 needle through L2-L3 or L3-L4 space. Loss of resistance techniques used to find the space. Epidural test dose of lidocaine ml 3 2% + μ / ml 5 epinephrine injected into the epidural space to ensure the integrity. After injected 15ml Marcaine 0/5%, the patient is given into supine position.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hospital

Full name of responsible person

Dr. Shima Motvali

Street address

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Afshin Gholipour

Street address

Moalem Square

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran University of Medical Sciences

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

Emam Hospital

Full name of responsible person

Dr. Afshin Gholipour

Position

Specialist

Other areas of specialty/work**Street address**

Amirmazandarani Street

City

Sari

Postal code**Phone**

+98 11 3336 1700

Fax**Email**

dr.motvali@gmail.com

Web page address

dr.motvali@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Pharmaceutical Science Research Center

Full name of responsible person

Dr. Aroona Chabra

Position

Pharm. D

Other areas of specialty/work**Street address**

Mazandaran University of Medical Sciences

City

Sari

Postal code**Phone**

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Fax**Email****Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Emam Hospital

Full name of responsible person

dr. Shima Motvali

Position

Specialist

Other areas of specialty/work**Street address**

Amirmazandarani Street

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Postal code**Phone**

+98 11 3336 1700

Fax**Email****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*