

# 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% +  $\mu$  / 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

backache

#### 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% +  $\mu$  / 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**

00

**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

**City**

Sari

**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*