Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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aroona_chabra2@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 Class1-2(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; Sever 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
hearth 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
Speciallist
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
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Emam Hospital
Full name of responsible person
dr. Shima Motvali
Position
Specialist
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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

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