

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Clinical trial comparison of addition of Midazolam or Normal Saline to Bupivacaine in spinal anesthesia in patients with fracture of lower extremities

Protocol summary

Summary

Study purpose: Evaluation of the effect of intrathecal midazolam on block characteristic and control of postoperative pain in orthopedic surgery undergoing spinal anesthesia with bupivacaine. Design: randomized, double blind controlled with placebo. Inclusion criteria: taking Informed consent to enter the study; patients between 20-70 old age; ASA Physical status class 1 and 2. Exclusion criteria: Ischemic heart disease; hypertension; uncontrolled diabetes; valvular heart disease; coagulopathy; lumbar spinal column deformity; block failure due to technical problems; needs to extra sedative drugs. Sample size: 80 person. Intervention: Spinal anesthesia will be applied with 17.5 mg bupivacaine 0.5% in 3.5 ml plus 2.5 mg midazolam in 0.5 ml (total volume 4 ml) in study group, and 17.5 mg bupivacaine 0.5% in 3.5 ml plus 0.5 ml normal saline (total volume 4 ml) in control group. Main outcome measures: Level of sensory block using cold cotton will be measured every one minute and whenever the same results will be gained in the four consecutive measurements, the detected dermatom will be recorded as the peak sensory block level. At the end of the surgery, when the patient is transferred to post anesthesia care unit (PACU) motor block will be measured and recorded using modified bromage scale. Time of regressing sensory block to the level of S1 dermatom, and regressing motor block to the bromage scale of 1, will be recorded and then the patients will be discharged from PACU.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016063028712N1**

Registration date: **2017-01-06, 1395/10/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-06, 1395/10/17

Registrant information

Name

Razieh Ebrahimi

Name of organization / entity

Kurdistan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparison of addition of Midazolam or Normal Saline to Bupivacaine in spinal anesthesia in

patients with fracture of lower extremities

Public title
Effects of intrathecal midazolam on block characteristic and control of postoperative pain

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: 1) take Informed consent to enter the study; 2) patients between 20-70 old age; 3) Physical status 1 and 2 classification of "American Society of Anesthesiologists"(ASA). Exclusion criteria: 1) Ischemic heart disease; 2) Hypertension; 3) Uncontrolled diabetes; 4) Valvular heart disease; 5) Coagulopathy; 6) Lumbar spinal column deformity; 7) Block failure due to technical problems; 8) Needs to extra sedative drugs.

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Computer generated randomization

Secondary Ids

1

Registry name
-

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kurdistan University of Medical Sciences

Street address
Kurdistan University of Medical Sciences , Pasdaran street, sanandaj

City
Sanandaj

Postal code
661777-13446

Approval date
2016-05-17, 1395/02/28

Ethics committee reference number
muk.rec.1395.82

Health conditions studied

1

Description of health condition studied
Regional anesthesia

ICD-10 code
T41.3

ICD-10 code description
Local anesthetics

Primary outcomes

1

Description
Intensity of sensory block

Timepoint
During first ten minute after block

Method of measurement
Cold cotton

2

Description
Intensity of motor block

Timepoint
During first ten minute after block

Method of measurement
Bromage scale

3

Description
Duration of sensory block

Timepoint
The time to regresion of sensory block to S1 in PACU

Method of measurement
Cold cotton

4

Description
Duration of motor block

Timepoint
The time to regression of motor block to bromage 1 in PACU

Method of measurement
Bromage scale

Secondary outcomes

1

Description

Pain scale

Timepoint

In discharge time and three hours later

Method of measurement

Numerical rating scale

2

Description

Nausea and vomiting

Timepoint

Time of block until discharge from recovery(PACU)

Method of measurement

Questionnaire

3

Description

Shivering

Timepoint

Time of block until discharge from recovery(PACU)

Method of measurement

Observation of face and extremities

4

Description

Hypotension

Timepoint

First 15 minutes after block every 2 minutes and then every 15 minutes

Method of measurement

Monitoring

5

Description

Bradycardia

Timepoint

First 15 minutes after block every 2 minutes and then every 15 minutes

Method of measurement

Monitoring

6

Description

The time to first analgesic request

Timepoint

3 hours after discharge of recovery

Method of measurement

File

Intervention groups

1

Description

Intervention group: Spinal anesthesia will be done with 17.5 mg bupivacaine 0.5% in 3.5 ml plus 2/5 mg

midazolam in 0.5 ml (total volume 4 ml) in study group

Category

Treatment - Drugs

2

Description

Control group: Spinal anesthesia will be done with 17.5 mg bupivacaine 0.5% in 3.5 ml plus 0.5 ml normal saline (total volume 4 ml) in control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Be'sat hospital of Sanandaj

Full name of responsible person

Dr.Farzad Sarshivi

Street address

Be'sat hospital, Keshavarz street, Sanandaj

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Kurdistan University of Medical Sciences

Full name of responsible person

Dr.Ebrahim Ghaderi

Street address

Kurdistan University of Medical Sciences, Pasharan street, Sanandaj

City

Sanandaj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Kurdistan 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

Kurdistan University of Medical Sciences

Full name of responsible person

Dr.Farzad Sarshivi

Position

Anesthesiologist

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Person responsible for scientific inquiries

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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