Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

The effects of adding intrathecal midazolam to bupivacaine in spinal anesthesia for pain reduction in lower limb orthopedic surgery

Protocol summary

Summary

The aim of this study is to determine the effect of adding Midazolam to Bupivacaine in spinal anesthesia.In this tripl blind clinical trial, 80 patients who undergo lower limb orthopedic surgery with spinal anesthesia are randomly divided into two groups of 40 person and equally are placed under spinal anesthesia with Bupivacaine.The first group 3ml Bupivacaine % 0.5 with 0.4 ml saline and the second group 3ml Bupivacaine % 0.5 with 0.4 ml Midazolam (2mg) will receive. In both groups the onset of sensory - motor block, the level of anesthesia, duration of anesthesia and adverse effects will be evaluated.Patient information will be compiled in check list and analyzed

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014021716612N1**
Registration date: **2014-06-06, 1393/03/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-06-06, 1393/03/16

Registrant information

Name
Khatereh Isazadehfar
Name of organization / entity
Ardabil University of Medical Sciences
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Iran (Islamic Republic of)
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+98 45 1225 1693
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Recruitment status

Recruitment complete

Funding source

Ardabil University of Medical Science

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2014-09-20, 1393/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of adding intrathecal midazolam to bupivacaine in spinal anesthesia for pain reduction in lower limb orthopedic surgery

Public title

The effects of adding intrathecal midazolam to bupivacaine in spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Candidate for lower limb orthopedic surgery, aged 15 to 80 years Exclusion criteria: Patients with impaired consciousness, lack of patient cooperation

Age

From **15 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ardabil University of Medical sciences

Street address
Ardabil University of Medical sciences, Ardabil, Iran

City
Ardabil

Postal code

Approval date
2013-07-14, 1392/04/23

Ethics committee reference number
arums.rec.92.11

Health conditions studied

1

Description of health condition studied
postoperative pain

ICD-10 code
Y83.8

ICD-10 code description
Other surgical procedures

Primary outcomes

1

Description
pain

Timepoint
per hour upto 6 hour after operation

Method of measurement
visual analoug scale

Secondary outcomes

1

Description
postoperative sedation

Timepoint
6 hour after surgery

Method of measurement
Ramsy scale

Intervention groups

1

Description
for control group3 ml bupivacain 0.5 % with 0.4 ml saline

Category
Prevention

2

Description
for intervention group 3 ml bupivacain 0.5% with 0.4 ml midazolam (2 mg)

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemi Hospital

Full name of responsible person
Masood Entezariasl

Street address

City
Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ardabil University of Medical Sciences

Full name of responsible person
Dr Akbar Pirzadeh

Street address
School of Medicine, Ardabil University of Medical Sciences, Ardabil, Iran

City
Ardabil

Grant name

Grant code / Reference number

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

Title of funding source
Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Dr.Khatereh Isazadehfar

Position

Assistant professor of Community Medicine

Other areas of specialty/work

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Professor of Anesthesiology

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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