

# 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

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#### 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

#### 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

#### 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 45 1225 1693

###### Email address

#### 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 group 3 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*

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## Person responsible for general inquiries

### Contact

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**Full name of responsible person**  
Dr.Khatereh Isazadehfar  
**Position**  
Assistant professor of Community Medicine  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

### Contact

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Dr. Masood Entezariasl  
**Position**  
Professor of Anesthesiology  
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Fatemy Hospital, Ardabil University of Medical  
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**City**  
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## Person responsible for updating data

### Contact

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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*