# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

12 Jun 2026

## The effect of adding intrathecal Magnesium Sulphate to Bupivacaine in spinal anesthesia for pain reduction in patient with lower limb orthopedic surgery

## Protocol summary

**Summary**
The aim of this study is to determine the effect of adding Magnesium Sulphate 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 1 ml saline and the second group 3ml Bupivacaine % 0.5 with 1 ml Magnesium Sulphate (50mg) 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: **IRCT2014042716612N2**
Registration date: **2014-07-04, 1393/04/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**
2014-07-04, 1393/04/13

**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**
kh.isazadehfar@arums.ac.ir

**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**
2014-09-21, 1393/06/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effect of adding intrathecal Magnesium Sulphate to Bupivacaine in spinal anesthesia for pain reduction in patient with lower limb orthopedic surgery

**Public title**
The effect of adding intrathecal Magnesium Sulphate 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**
2014-04-14, 1393/01/25
**Ethics committee reference number**
arums.rec.93.35

## 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 1 ml saline
**Category**
Prevention

### 2

**Description**
for intervention group 3 ml bupivacain 0.5% with 1 ml Magnesium Sulphate (50 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**
Khatereh Isazadehfar
**Position**
Assistant professor of Community Medicine
**Other areas of specialty/work**
**Street address**
Emam Khomeiny Hospital, Ardabil University of Medical Sciences
**City**
Ardabil
**Postal code**
**Phone**
+98 45 1225 1693
**Fax**
**Email**
isazadehfar@yahoo.com kh.isazadehfar@arums.ac.ir
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Ardabil University of Medical Scienses
**Full name of responsible person**
Masood Entezariasl
**Position**
Professor of Anesthesiology
**Other areas of specialty/work**
**Street address**
Fatemy Hospital, Ardabil University of Medical Sciences
**City**
Ardabil
**Postal code**
**Phone**
+98 45 1225 1688
**Fax**
**Email**
m.entezari@arums.ac.ir
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Ardabil University of Medical scienses
**Full name of responsible person**
Khatereh Isazadehfar
**Position**
Assistant professor of Community Medicine
**Other areas of specialty/work**
**Street address**
Emam Khomeiny Hospital, Ardabil University of Medical Sciences
**City**
Ardabil
**Postal code**
**Phone**
00
**Fax**
**Email**
isazadehfar@yahoo.com kh.isazadehfar@arums.ac.ir
**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*