

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jul 2026

### Effect of magnesium sulfate on reduction of need to opium, prolongation of block duration and pain after lower extremity fractures surgery operation

#### Protocol summary

##### Summary

The effect of IV infusion of mgso4 was evaluated on less need to opium and prolongation of block duration In patients under lower extremity surgeries with spinal anesthesia. Study was carried out in a double blind manner, one centric clinical trial and by simple randomized method (closed packet and the selection of painted cards) on sixty patients with 45\_75 year's old, candidate for elective surgery of lower extremity fractures with spinal anesthesia in Rajai hospital of Qazvin. All patients were in American Society of Anesthesia ( ASA) class I and II and drug abusers or magnesium supplement receivers were excluded. Magnesium group (M) after 15 minutes of spinal anesthesia received 50mg/kg mgso4 20% in 250 cc NACL 0.9% in 20 minutes and control group(C) received only 250 cc NACL during the same time. At the end of operation a patient control analgesia device (pca) was used for two groups, contain morphine 20m, ondancetron 8mg, apotel 2 gr and dexamethasone 8 mg (in the first 24 hours) and. dosage of all drugs was change to one half for the second 24h. The amount of opium consumption, pain and duration of block were the same as primary variable outcome and the general pleasure and quality of sleep were as the second variable outcome, in the time courses of 4, 6, 12, 24 and 48 after operation.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016022825676N3**

Registration date: **2016-05-07, 1395/02/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-05-07, 1395/02/18

##### Registrant information

###### Name

Hamid Kayalha

###### Name of organization / entity

Qazvin University of Medical Sciences & Health Services

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 3332 1007

###### Email address

hkayalha@qums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for research Qazvin University of Medical Sciences

##### Expected recruitment start date

2015-06-22, 1394/04/01

##### Expected recruitment end date

2016-02-20, 1394/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of magnesium sulfate on reduction of need to opium, prolongation of block duration and pain after lower extremity fractures surgery operation

##### Public title

Effect of magnesium sulfate on reduction of need to opium after lower extremity fractures surgery operation

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

Inclusion criteria: 45\_75 years old; ASA 1 & 2; undergoing elective surgery of lower extremity fractures ; spinal anesthesia; pleasure in entrance to study. Exclusion criteria: diabetes; hypertension; myopathy; opium or alcohol addiction; Advanced heart disease and heart block inside; kidney & liver disorders; magnesium supplement & calcium channel blocker receivers; pregnant patients & neurologic disorders.

#### **Age**

From **45 years** old to **75 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)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

Random sampling is based on selection of colorful cards.

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics Committee of the University of Medical Sciences

###### **Street address**

Qazvin, Shahid Bahonar Blvd

###### **City**

Qazvin

###### **Postal code**

3419759811

##### **Approval date**

2015-12-09, 1394/09/18

##### **Ethics committee reference number**

IR.QUMS.REC.1394.232

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

lower limb fracture

##### **ICD-10 code**

T12

##### **ICD-10 code description**

Fracture of lower limb, level unspecified

### **Primary outcomes**

#### **1**

##### **Description**

Pain

##### **Timepoint**

Immediately after operation and 4, 8, 12, 24 & 48 Hours after

##### **Method of measurement**

Score of pain in Visual analog scale (VAS)

#### **2**

##### **Description**

Amount of analgesic consumption

##### **Timepoint**

24 & 48 hours after operation

##### **Method of measurement**

Patient control analgesia poump

#### **3**

##### **Description**

Duration of spinal block

##### **Timepoint**

Since start of spinal anesthesia till return of sensory motor block after operation

##### **Method of measurement**

Objective

### **Secondary outcomes**

#### **1**

##### **Description**

Quality of sleep

##### **Timepoint**

The first night after operation

##### **Method of measurement**

Score of sleep in Visual analog scale (VAS)

#### **2**

##### **Description**

Patients satisfaction of pain control

##### **Timepoint**

Immediately after operation and 4, 8, 12, 24 & 48 Hours after

##### **Method of measurement**

Score of satisfaction based on Visual analog scale (VAS)

## Intervention groups

1

### Description

In magnesium group (M) after spinal anesthesia, 15minute later 50mg/kg from 20% magnesium solution in 250 cc Normal saline in 20 minutes administered.

### Category

Treatment - Drugs

2

### Description

Control group (c), after spinal anesthesia 15 minuits later from block received only 250cc normal saline.

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Rajee Hospital

#### Full name of responsible person

Parastu Izadpanahi

#### Street address

Rajee Hospital, Padegan Avenu, Qzvin.

#### City

Qazvin

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Vice Chancellor for research Qazvin University of Medical Sciences

#### Full name of responsible person

Dr. Taghi Naserpour

#### Street address

Shahid Bamonar Blvd, Qazvin

#### City

Qazvin

### 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 Qazvin 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

Qazvin University of Medical Sciences

#### Full name of responsible person

Dr. Parastu Izadpanahi

#### Position

Assistant of Anesthesiology

#### Other areas of specialty/work

#### Street address

Rajee Hospital, Padegan Avenu, Qzvin

#### City

Qazvin

#### Postal code

#### Phone

+98 28 3376 0620

#### Fax

#### Email

vcrc92@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Qazvin University Of Medical Sciences

#### Full name of responsible person

Dr. Hamid Kayalha

#### Position

Assistant Professor of Anesthesiology

#### Other areas of specialty/work

#### Street address

Medical School, Qazvin University Of Medical Sciences, Shahid Bamonar Blvd

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Qazvin University of Medical Sciences

#### Full name of responsible person

Dr. Parastu Izadpanahi

#### Position

Assistant of Anesthesiology

#### Other areas of specialty/work

#### Street address

|                                                           |                                  |
|-----------------------------------------------------------|----------------------------------|
| <b>City</b>                                               | <i>empty</i>                     |
| Qazvin                                                    |                                  |
| <b>Postal code</b>                                        | <i>empty</i>                     |
| <b>Phone</b>                                              | <b>Statistical Analysis Plan</b> |
| 00                                                        | <i>empty</i>                     |
| <b>Fax</b>                                                | <b>Informed Consent Form</b>     |
| <b>Email</b>                                              | <i>empty</i>                     |
| <b>Web page address</b>                                   | <b>Clinical Study Report</b>     |
|                                                           | <i>empty</i>                     |
| <b>Sharing plan</b>                                       | <b>Analytic Code</b>             |
|                                                           | <i>empty</i>                     |
| <b>Deidentified Individual Participant Data Set (IPD)</b> | <b>Data Dictionary</b>           |
|                                                           | <i>empty</i>                     |