

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 20mg, 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

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Name of organization / entity

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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

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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

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Person responsible for updating data

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Position

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Other areas of specialty/work

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