Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation effect of Intravenous Magnesium Sulfate on pain rate afterL4,L5,S1 lumbar spine surgeryin clinical trial

Protocol summary

Study aim
Studying the effects of intravenous magnesium sulfate on pain after lumbar disc surgery at L4, L5 and L5, S1

Design
A controlled, double-blind, randomized, phase 3 clinical trial with parallel groups on 80 patients. The rand function of Excel software was used for randomization.

Settings and conduct
Patients referred to Imam Khomeini Hospital in Sari. Random allocation method will be used. In two intervention groups (receiving magnesium sulfate) and control (receiving normal saline). The blocking process is done with the Random allocation software. Also, the size of each block (4, 6, etc.) is determined by the software. In this design, blinding is done by a random double-blind method. In this way, the person evaluating the patient and the patient themselves do not know the groups to which the patient has been assigned.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Confirmed diagnosis by physical examination, CT scan and MRI, patient willingness to participate in the study and informed consent, candidate for non-emergency discectomy surgery, people under 50 years of age, people with normal kidney function, people with no history of heart problems. Exclusion criteria: Patient unwillingness to participate in the study, emergency discectomy surgery, known allergy to one of the study drugs, use of narcotic analgesics up to 12 hours before the intervention

Intervention groups
Intervention group: Magnesium sulfate is injected once, at a dose of 50 mg/kg body weight, half an hour before the operation, from Darupakhsh Company, made in Iran. Control group: Placebo: Normal saline is injected once, at a dose of 50 mg/kg body weight, half an hour before the operation, from Darupakhsh Company, made in Iran.

Main outcome variables
The primary outcome of the study was the severity of patients' pain and the amount of narcotics consumed.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250630066304N1**
Registration date: **2025-07-13, 1404/04/22**
Registration timing: **prospective**

Last update: **2025-07-13, 1404/04/22**
Update count: **0**

Registration date
2025-07-13, 1404/04/22

Registrant information

Name
Samira Sobhani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 3336 1700

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ssobhani1983@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-22, 1404/04/31

Expected recruitment end date
2025-09-22, 1404/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation effect of Intravenous Magnesium Sulfate on pain rate afterL4,L5,S1 lumbar spine surgeryin clinical trial

Public title

Evaluation effect of Intravenous Magnesium Sulfate on pain rate afterL4,L5,S1 lumbar spine surgeryin clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirming the diagnosis with a physical examination, CT scan, and MRI Patient's willingness to participate in the study and obtaining informed consent Candidate for non-emergency discectomy surgery People under 50 years old People with normal kidney function People with no history of heart problems

Exclusion criteria:

The patient's unwillingness at any time to continue participating in the study Emergency discectomy surgery Known allergy to one of the study drugs Use of narcotic painkillers up to 12 hours before the intervention Alcohol or drug abuse

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation method will be used. To randomly allocate samples to two intervention groups (receiving magnesium sulfate) and control (receiving normal saline), the blocking method will be used. The blocking process is done with the Random allocation software. Also, the size of each block (4, 6, etc.) is determined by the software.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this design, blinding is done in a double-blind randomization manner. In this way, the patient's assessor and the patient themselves do not know which groups the patient is assigned to. The SNOSE method will be used to conceal (blind) the randomization. This method is one of the common methods for concealing randomization. The interventions are provided to the anesthetist in sealed envelopes. The participants, the principal investigator, and the anesthetist in the neurosurgery room, who are usually responsible for caring for the patients, are unaware of the group allocation, which groups received which drugs, and the type of study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Mazandaran University of Sari Medical Sciences, Imam Hospital

Street address

Imam Khomeini Medical Training Center, Amir Mazandarani Boulevard, Sari, Iran

City

Sari

Province

Mazandaran

Postal code

48166-33131

Approval date

2025-05-12, 1404/02/22

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1404.024

Health conditions studied

1

Description of health condition studied

Lumbar disc surgery L4, L5, S1

ICD-10 code

M51.16

ICD-10 code description

Intervertebral disc disorders with radiculopathy, lumbar region

Primary outcomes

1

Description

Pain intensity

Timepoint

After surgery and before leaving recovery, 4 and 24 hours after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description
The amount of nausea and vomiting
Timepoint
After surgery and before leaving recovery, 4 and 24 hours after surgery
Method of measurement
Visual Analogue Scale

Intervention groups

1

Description
Intervention group:Magnesium sulfate is injected once into the patient at a dose of 50 mg/kg of body weight half an hour before the operation from Darupakhsh Pharmaceutical Company, made in Iran.
Category
Treatment - Surgery

2

Description
Control group:Placebo normal saline at a dose of 50 mg/kg body weight half an hour before the operation, injected once, from Darou Pashaek Company, made in Iran, is injected into the patient.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital, Sari
Full name of responsible person
Samira Sobhani
Street address
Imam Khomeini Medical Training Center, Amir Mazandarani Boulevard, Sari, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Ahmadali Enayati
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Research and Technology Center, Mazandaran University of Medical Sciences, Moallem Square, Sari, Iran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Samira Sobhani
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available