

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Comparison of different doses of Intravenous magnesium sulfate on intraoperative anesthetic drugs usage and post operative pain in Posterior Spinal Fusion surgery

Protocol summary

Study aim

Reduce the use of anesthesia, their complications, pain during and after surgery

Design

After obtaining the approval of ethics committee, candidates for posterior spinal fusion surgery who meet the inclusion criteria will be selected and patients will be randomly divided into two groups M (1, 2, 3) and S (control) that receive equal volume of placebo (normal saline). Five minutes before the onset of anesthesia in group M, a dose of 50 mg/kg of intravenous magnesium sulfate was given in 15 minutes and vanfusion doses of 10, 15, 20 mg/kg/hr followed up to the end of the operation. The S group was given a dose of bolus with the same volume of normal saline during 15 minutes of vanfusion.

Settings and conduct

Patients aged 18 to 65 years will be candidates for elective PSF surgery referred to Loghman Hakim Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-65 years, no history of drug allergy, no history of thromboembolism, no liver, heart or kidney failure, and coagulation disorders, no anticoagulant drugs, no severe obesity, no neuromuscular disease, no calcium channel blockers, physical class of American Society of Anesthesiology I, II (ASA) and patient satisfaction to participate in the study
Exclusion criteria: Surgery time greater than 5 hours
Changing the Surgical Procedure
Bleeding more than 2 liters and requires massive transfusion. Sustained blood pressure drop of more than 25% basal

Intervention groups

Patients in group M were given one dose of 50 mg/kg of intravenous magnesium sulfate in 15 minutes and vanfusion doses of 10, 15, 20 mg/kg, followed up to the end of the operation. The S group was given a dose of

normal saline bolus for 15 minutes.

Main outcome variables

Blood pressure; Volume of bleeding during surgery; Magnesium Sulfate Dosage; Depth of anesthesia; Pain after the operation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230810059108N1**
Registration date: **2023-08-21, 1402/05/30**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-21, 1402/05/30**

Update count: **0**

Registration date

2023-08-21, 1402/05/30

Registrant information

Name

Neshat Abdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 078 6983

Email address

neshat.a15@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-13, 1402/05/22

Expected recruitment end date

2024-08-12, 1403/05/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of different doses of Intravenous magnesium sulfate on intraoperative anesthetic drugs usage and post operative pain in Posterior Spinal Fusion surgery

Public title

Effect of magnesium sulfate on anesthesia consumption and pain after spinal surgery

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18-65 years no history of drug sensitivity no history of thromboembolism no liver, heart or kidney failure, and coagulation disorders no anticoagulant drugs usage no severe obesity no neuromuscular disease no calcium channel blockers usage physical class of American Society of Anesthesiology I,II (ASA) and patient satisfaction to participate in the study

Exclusion criteria:

Surgery time greater than 5 hours Changing the Surgical Procedure Bleeding more than 2 liters and requires massive transfusion Sustained blood pressure drop of more than 25% basal BP

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this clinical trial study, after obtaining the approval of ethics committee, candidates for posterior spinal fusion surgery who meet the inclusion criteria will be selected and patients will be randomly divided into two groups M (1, 2, 3) and S (control) that receive equal volume of placebo (normal saline). Each patient will be given a sealed envelope containing the information of the study or control group and will be opened by the designated nurse in the operating room. Patients are blind to the study group or placebo. But the anesthesiologist in the operating room will be aware of the type of drug received and the drugs studied by an anesthesiologist will be prepared and prescribed for everyone, patients and other members of the research group will not be aware of the intervention group. Simple random sampling is using random table of numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this clinical trial study, after obtaining the approval of ethics committee, candidates for posterior spinal fusion surgery who meet the inclusion criteria will be selected and patients will be randomly divided into two groups M (1, 2, 3) and S (control) that receive equal volume of placebo (normal saline). Each patient will be given a sealed envelope containing the information of the study or control group and will be opened by the designated nurse in the operating room. Patients are blind to the study group or placebo. But the anesthesiologist in the operating room will be aware of the type of drug received and the drugs studied by an anesthesiologist will be prepared and prescribed for everyone, patients and other members of the research group will not be aware of the intervention group

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Science

Street address

Loghman Hakim Hospital, Makhsoos Ave. South Kargar Ave

City

Tehran

Province

Tehran

Postal code

1473656475

Approval date

2023-07-25, 1402/05/03

Ethics committee reference number

IR.SBMU.MSP.REC.1402.187

Health conditions studied**1****Description of health condition studied**

Magnesium Sulfate

ICD-10 code

Z98.8

ICD-10 code description

Other specified postsurgical states

Primary outcomes

1

Description

Postoperative pain

Timepoint

6.12.24 hours after surgery

Method of measurement

Numerical Rating Scale

Secondary outcomes

1

Description

Dosage of Anesthetic Drugs

Timepoint

During surgery

Method of measurement

Bispectral Index

Intervention groups

1

Description

First Intervention group (M1): At first, 50 mg/kg magnesium sulfate is given intravenous bolus for 15 minutes and then infusion of intravenous magnesium sulfate is 10 mg/kg/h.

Category

Treatment - Drugs

2

Description

Second intervention group (M2): At first, 50 mg/kg magnesium sulfate is given intravenous bolus within 15 minutes and then infusion of intravenous magnesium sulfate is 15 mg/kg/h.

Category

Treatment - Drugs

3

Description

Third intervention group (M3): First, 50 mg/kg of magnesium sulfate is given intravenous bolus during 15 minutes and then the infusion of 20 mg/kg/hr of magnesium sulfate.

Category

Treatment - Drugs

4

Description

Control group(S): The control group will be given a dose of bolus normal saline equal to the volume of the intervention group during 15 minutes of continuous to the end of the operation.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim Hospital

Full name of responsible person

Dr Masood Nashibi

Street address

Loghman Hakim Hospital.Makhsos Ave .South Kargar Ave

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1333635445

Phone

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Email

neshat.a15@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

Loghman Hakim Hospital.Makhsos Ave.South Kargar Ave

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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

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Neshat Abdi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The whole data is potentially shareable after making people unidentifiable.

When the data will become available and for how long

Start of access period 1 month after publication of results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For the purpose of academic research

From where data/document is obtainable

neshat.a15@gmail.com

What processes are involved for a request to access data/document

For the purpose of academic research

Comments