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 neuromascular 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 neuromascular 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 committe 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.Makhsoos Ave .South Kargar Ave
City
Tehran
Province
Tehran
Postal code
1333635445
Phone
+98 912 078 6983
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.Makhsoos Ave.South Kargar Ave
City
Tehran
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Postal code
1333635445
Phone
+98 912 078 6983
Email
neshat.a15@gmail.com
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

Street address

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Person responsible for scientific inquiries

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Position

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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