Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Analgesic effects of combination of preoperative intravenous magnesium sulfate and oral pregabalin on postoperative pain in patients undergoing posterior lumbar spinal fusion surgery

Protocol summary

Study aim

Assessing the analgesic effects of combination of preoperative intravenous magnesium sulfate and oral pregabalin on postoperative pain in patients undergoing posterior lumbar fusion surgery

Design

This study is a randomized, controlled, double-blind, four-arm parallel group, placebo-controlled phase 3 trial on 80 patients.

Settings and conduct

This study includes 80 patients undergoing posterior lumbar spinal fusion surgery. Randomization and concealment will be carried out using sealed opaque envelope. Patients will be assessed in terms of the study outcomes in 0, 4, 8, 12, 24, 48 hours postoperatively.

Participants/Inclusion and exclusion criteria

Inclusion criteria includes patients between the ages of 18 and 70 years and patients undergoing posterior lumbar spinal fusion surgery. Exclusion criteria involves patients with hepatic dysfunction (transaminases above normal levels) and renal failure (creatinine >150 µmol/l); cardiac dysfunction (ejection fraction <40); neurological disorder, myopathy, or history of psychological disorder (e.g. current treatment with antipsychotic and antidepressant medications); known sensitivity or contraindication to dugs used in the study; preoperative opioid use or regular opioid use due to chronic pain (pain more than 3 months); preoperative administration of calcium channel blocker; hypermagnesemia.

Intervention groups

Patients in the present study will be randomly assigned to four groups including preoperative intravenous (IV) magnesium sulfate and oral pregabalin (MP) group, preoperative IV magnesium sulfate (M) group, preoperative oral pregabalin (P), and control (C) group which receives the placebo.

Main outcome variables

Primary outcome of the study is cumulative morphine consumption (mg). Secondary outcomes include visual analogue scale (VAS, 0-10) for pain at rest, Ramsay sedation scale (RSS), and postoperative nausea and vomiting (PONV).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190703044091N1**
Registration date: **2020-09-14, 1399/06/24**
Registration timing: **prospective**

Last update: **2020-09-14, 1399/06/24**
Update count: **0**

Registration date

2020-09-14, 1399/06/24

Registrant information

Name

Roozbeh Tavanaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-19, 1399/06/29

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Analgesic effects of combination of preoperative intravenous magnesium sulfate and oral pregabalin on postoperative pain in patients undergoing posterior lumbar spinal fusion surgery

Public title
Effects of magnesium sulfate and pregabalin on postoperative pain in posterior lumbar spinal fusion surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients between the ages of 18 and 70 years Patients undergoing posterior lumbar spinal fusion surgery
Exclusion criteria:
Patients with hepatic dysfunction (transaminases above normal levels) and renal failure (creatinine >150 µmol/l) Cardiac dysfunction (ejection fraction <40) Neurological disorder, myopathy, or history of psychological disorder (e.g. current treatment with antipsychotic and antidepressant medications) Known sensitivity or contraindication to dugs used in the study Preoperative opioid use or regular opioid use due to chronic pain (pain more than 3 months) Preoperative administration of calcium channel blocker Hypermagnesemia
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients in the present study will be randomized using the sealed opaque envelope. All patients, investigators, outcome assessors, and medical staff, in the present study will be blinded to the study intervention. Study drugs and placebo will be indistinguishable during the course of the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
All patients, investigators, outcome assessors, and medical staff, in the present study will be blinded to the study intervention.
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 Sciences
Street address
Shohada-e-Tajrish Hospital, Qods Sq., Tajrish, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1989934148
Approval date
2020-08-09, 1399/05/19
Ethics committee reference number
IR.SBMU.RETECH.REC.1399.474

Health conditions studied

1

Description of health condition studied
Fusion of spine, lumbar region
ICD-10 code
M43.26
ICD-10 code description
Fusion of spine, lumbar region

Primary outcomes

1

Description
Comulative morphine consumption
Timepoint
Baseline (before the operation), 4, 8, 12, 24 hours postoperatively
Method of measurement
Cumulative morphine consumption by assessing the patient controlled analgesia (PCA) pump

Secondary outcomes

1

Description
Visual analogue scale (VAS, 0-10) for pain at rest
Timepoint
Baseline (before the operation), 4, 8, 12, 24 hours postoperatively
Method of measurement
Visual analogue scale

2

Description
Posoperative nausea and vomiting (PONV)
Timepoint
In 24 hours postoperatively
Method of measurement
Number of episodes patient experiencing nausea and vomiting

3

Description
Ramsay sedation scale (RSS)
Timepoint
Baseline (before the operation), 4, 8, 12, 24 hours postoperatively
Method of measurement
Patients will be divided into 6 groups according to their level of sedation (from severe agitation to deep coma)

Intervention groups

1

Description
Intervention group 1: Patients in this group (MP) will receive preoperative intravenous infusion of 50 mg/kg magnesium sulfate mixed with 200 ml of normal saline and 300 mg pregabalin orally. All the medications will be administered 1 hour before the operation. Infusions will be given over 30 minutes.
Category
Treatment - Drugs

2

Description
Intervention group 2: Patients in this group (M) will receive preoperative intravenous infusion of 50 mg/kg magnesium sulfate mixed with 200 ml and a placebo capsule. All the medications will be administered 1 hour before the operation. Infusions will be given over 30 minutes.
Category
Treatment - Drugs

3

Description
Intervention group 3: Patients in this group (P) will receive preoperative intravenous infusion of 200 ml of normal saline and 300 mg pregabalin orally. All the medications will be administered 1 hour before the operation. Infusions will be given over 30 minutes.
Category
Treatment - Drugs

4

Description
Control group: Patients in this group (C) will receive preoperative intravenous infusion of 200 ml of normal saline and a placebo capsule. All the medications will be administered 1 hour before the operation. Infusions will be given over 30 minutes.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada-e Tajrish hospital
Full name of responsible person
Saeed Oraee-Yazdani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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7th Floor, Bldg No.2 SBMUS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, 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
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
Roozbeh Tavanaei
Position
Research associate
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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