# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

28 May 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)

**Phone**

+98 21 2270 1022

**Email address**

rtavanaei@sbmu.ac.ir

**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
**Street address**
Shohada-e-Tajrish Hospital, Qods Sq., Tajrish, Tehran, Iran
**City**
Tehran
**Province**
Tehran
**Postal code**
1989934148
**Phone**
+98 21 2270 1022
**Email**
saeed_o_yazdani@sbmu.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Afshin Zarghi
**Street address**
7th Floor, Bldg No.2 SBMUS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
**City**
Tehran
**Province**
Tehran
**Postal code**
19839-63113
**Phone**
+98 21 2270 1022
**Email**
Intl_office@sbmu.ac.ir
**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

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurosurgery

**Street address**

Functional Neurosurgery Research Center (FNRC), SBMU Shohada-E-Tajrish Educational Hospital, Tajrish Sq., Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1989934148

**Phone**

+98 21 2270 1022

**Fax**

**Email**

rtavanaei@sbmu.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Saeed Oraee-Yazdani

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurosurgery

**Street address**

Functional Neurosurgery Research Center (FNRC), SBMU Shohada-E-Tajrish Educational Hospital, Tajrish Sq., Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1989934148

**Phone**

+98 21 2270 1022

**Fax**

**Email**

saeed_o_yazdani@sbmu.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohammadhosein Akhlaghpasand

**Position**

Research associate

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurosurgery

**Street address**

19899 , Shahrdari St, Tehran, Tehran Province, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1989934148

**Phone**

+98 21 2270 1022

**Fax**

**Email**

akhlaghpasandm@yahoo.com

**Web page address**

## 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 |