

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative effect of ketamine and magnesium sulfate on pain control after spine surgery.

Protocol summary

Study aim

Comparative effect of ketamine and magnesium sulfate on pain control after spine surgery.

Design

Clinical trial with 2 interventional group, Block randomization, 43 subjects in each group, with parallel groups, double blind

Settings and conduct

Sampling is simple randomization. The letter A belongs to the magnesium sulfate group with an initial dose of 50 mg / kg and the letter B belongs to the ketamine group with an initial dose of 0.5 mg / kg. This process will continue until 36 people are selected for each group. Anesthesia induction will be performed by an anesthesiologist who is aware of the design and has no role in the process and outcome of the study. The patient's hemodynamics will be recorded in the operating room throughout the surgery, and the time of onset of pain and the first dose received and pain will be recorded based on the VAS.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Class 1 or 2 ASA , Age range 18-65 years ,Candidate for laminectomy by posterior lumbar spine CD. Exclusion criteria: Previous history of lumbosacral surgery, History of schizophrenia and use of antipsychotic drugs, History of calcium channel blockers, History of neuropathy and myopathy, History of kidney damage requires dialysis in the past, Presence of conduction system abnormalities in the ECG taken from the patient, History of ketamine allergy, The length of stay after surgery is less than 48 hours.

Intervention groups

First group: Magnesium sulfate 50 mg/kg by infusion over 20 minutes; Magnesium sulfate 500 mg/hr as an infusion in a pain pump lasts up to 48 hours after surgery. Second group: ketamine 0.5 mg/kg in bolus 2 minutes before surgical incision; Ketamine 2.5 µ /kg/hr as an infusion in a pain pump lasts up to 48 hours after surgery.

Main outcome variables

Determining the mean score of postoperative pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170413033408N6**

Registration date: **2021-03-11, 1399/12/21**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-11, 1399/12/21**

Update count: **0**

Registration date

2021-03-11, 1399/12/21

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3254 9891

Email address

dr.mojaveraghili@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-23, 1399/12/05

Expected recruitment end date

2022-02-24, 1400/12/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effect of ketamine and magnesium sulfate on pain control after spine surgery.

Public title

Comparison of the effect of ketamine and magnesium sulfate on pain control after spinal surgery.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Class 1 or 2 ASA based on the physical condition of the American Anesthesia Association. Subjects in the age range of 18-65 years. Candidate for laminectomy and discectomy and screw and plaque implantation by posterior lumbar and sacral spine CD.

Exclusion criteria:

Previous history of lumbosacral surgery. History of schizophrenia and use of antipsychotic drugs. History of calcium channel blockers. History of neuropathy and myopathy. History of kidney damage requires dialysis in the past. Presence of conduction system abnormalities in the ECG taken from the patient. History of ketamine allergy. The length of stay after surgery is less than 48 hours.

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data and Safety Monitoring Board

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

How to assign patients to one of the two drug groups will be done based on the permutation block method. A random sequence of letters A and B will be generated in 18 quadruple blocks and will be provided to one of the members of the research team. This member will not interfere in the selection of samples. The letter A belongs to the magnesium sulfate group and the letter B belongs to the ketamine group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Anesthesia induction will be performed by a design-conscious anesthesiologist who will have no role in the process and outcome of the study, and the preparation of pumps that are similar in appearance (size, shape, volume, manufacturer) will be performed by the recovery nurse and the physician in charge will have no information about its contents and will be blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan University of Medical Sciences

Street address

Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology of Gorgan, Gorgan, Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2021-01-24, 1399/11/05

Ethics committee reference number

IR.GOUMS.REC.1399.343

Health conditions studied

1

Description of health condition studied

Candidate for laminectomy and discectomy and screw and plaque implantation by posterior lumbar and sacral spine CD

ICD-10 code

M96.1

ICD-10 code description

Postlaminectomy syndrome, not elsewhere classified

2

Description of health condition studied

Spondylopathies

ICD-10 code

M45-M49

ICD-10 code description

Spondylopathies

Primary outcomes

1

Description

Postoperative pain score

Timepoint

Pain score since entering recovery, 6, 12, 24, 36 and 48 hours after surgery will be measured.

Method of measurement

Based on VAS measurement criteria

2

Description

Postoperative sedation rate

Timepoint

Sedation score since entering recovery, 6, 12, 24, 36 and 48 hours after surgery will be measured.

Method of measurement

Based on RSS measurement criteria

3

Description

hemodynamic changes

Timepoint

The patient's hemodynamic monitoring will be performed from the time of entering the operating room until the end of the operation.

Method of measurement

Hemodynamic criteria (heart rate, systolic, diastolic, and mean arterial blood pressure (MABP), arterial oxygen saturation) of the patient will be measured by Saadat monitoring.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Magnesium sulfate 50 mg / kg by infusion with CVE = 5 ml / kg over 20 minutes; Magnesium sulfate 500 mg / hr as an infusion in a pain pump lasts up to 48 hours after surgery.

Category

Treatment - Drugs

2

Description

Intervention group: ketamine 0.5 mg / kg in bolus form immediately after patient positioning and 2 minutes before surgical incision; Ketamine 2.5 μ / kg / hr as an infusion in a pain pump lasts up to 48 hours after surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gorgan 5 Azar Educational and Medical Center

Full name of responsible person

Seyed Babak Mojaver Aghili

Street address

Gorgan-Sari road 4th kilometers, Golestan University of Medical Sciences, School of Medicine - Anesthesiology Department

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Postal code

4917761551

Phone

+98 17 3223 8363

Email

drbabaka35@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Mohammad Reza Honarvar

Street address

Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology of Gorgan, Golestan, Iran

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Phone

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Email

honarvar@goums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Seyed Babak Mojaver Aghili

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology of Gorgan, Golestan, Iran

City

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Postal code

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Email

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

Seyed Babak Mojaver Aghili

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

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Email

drbabaka35@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Gorgan University of Medical Sciences

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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the main outcome

When the data will become available and for how long

Since 2020

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

No manipulation, mentioning the data reference

From where data/document is obtainable

Seyed Babak Mojaver Aghili, drbabaka35@gmail.com, Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology, Gorgan, Golestan, Iran.

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

sending an email, complete the personal and professional characteristics with documentation

Comments