

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of Ketamine and magnesium sulfate gargle on postoperative sore throat in patient under laminectomy

Protocol summary

Study aim

The effect of ketamine and magnesium sulfate gargle on postoperative sore throat

Design

Patients who are candidates for Laminectomy surgery are randomly divided into three groups using a table of random numbers and each group consists of 20 people. Groups: ketamine group, magnesium sulfate group, and control group. The sample size was determined to be 60 and divided into 3 groups. a two-blind clinical trial with a control group

Settings and conduct

Patients who are candidates for Laminectomy surgery at Shohada Tajrish Hospital are divided into three groups, and participants do not have information about the groups and receiving medication or placebo

Participants/Inclusion and exclusion criteria

All patients between 25 and 75 years old are candidates for Laminectomy surgery Exclude criteria: History of high blood pressure or heart disease and upper respiratory tract infection

Intervention groups

Three groups: The first group gargles ketamine with 5% dextrose serum The second group gargles with magnesium sulfate with 5% dextrose and the third group (control) gargles as a placebo.

Main outcome variables

Postoperative sore throat

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210216050379N1**

Registration date: **2021-05-31, 1400/03/10**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-31, 1400/03/10**

Update count: **0**

Registration date

2021-05-31, 1400/03/10

Registrant information

Name

Hamidreza Azizifarsani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2274 1174

Email address

h.faresani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2021-11-06, 1400/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Ketamine and magnesium sulfate gargle on postoperative sore throat in patient under laminectomy

Public title

The effect of Ketamine and magnesium sulfate gargle on postoperative sore throat in patient under laminectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients (25-75 old) with ASA class 1,2(American Society of Anesthesiology) simple intubation

Exclusion criteria:
congestive heart failure, difficult intubation chronic respiratory ,kidney and liver disease

Age
From **25 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
single randomized, individual, computerized random number table we introduce a number for each patient, and then by assay computerized random, number table, the patients will be divided in 3 experimental groups. this randomization will be done by a principal investigator, and the nurse, the physician, and the person who does the analytical evaluation will be blind related to this randomization.

Blinding (investigator's opinion)
Double blinded

Blinding description
The Anesthetist responsible for delivering anesthesia will not be informed about the patients group. the person who will record the data,will be blind to the groups

Placebo
Used

Assignment
Parallel

Other design features
NO

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Science,Arabi Ave, Daneshjoo Blvd, Velenjak,Tehran

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2021-02-15, 1399/11/27

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1399.349

Health conditions studied

1

Description of health condition studied

Pain in throat

ICD-10 code

pain in th

ICD-10 code description

R07.0

Primary outcomes

1

Description

Sore throat after surgery

Timepoint

Upon entering recovery, 2, 12 and 24 hours after surgery

Method of measurement

visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group 1: 1 mg per kg body weight of ketamine (Rotex Medica Company) with 30 cc of 5% dextrose serum is gargled by the patient for 30 seconds 15 minutes before the start of anesthesia.

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group 2: Magnesium sulfate group: 30 mg per kg body weight of 20% magnesium sulfate (Pasteur Institute) with 30 cc of 5% dextrose, 15 minutes before the start of anesthesia, the patient gargles for 30 seconds.

Category

Treatment - Drugs

3

Description

Control group: 30 cc of 5% dextrose serum is gargled by the patient for 30 seconds 15 minutes before the start of anesthesia.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

shohada tajrish hospital

Full name of responsible person

dr. Mehrdad Feizi

Street address

Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences, Valiasr St., corner of Niayesh, Tehran

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1989934148

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h.faresani@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seied Ali Ziayi

Street address

Third floor, school of Medicine, near Taleghani Hospital, Evin, Shahid Chamran High way

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Research Department of Shahid Beheshti University of medical science

Proportion provided by this source

50

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

Hamidreza Azizi Faresani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shayesteh Khorasanizadeh

Position

Assistant professor

Latest degree

Specialist

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Azizi Faresani

Position

student

Latest degree

Medical doctor

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Medical Pharmacy

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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

Data and documentation after being unidentified are also
published as the main consequence

When the data will become available and for how long

7/11/2021

To whom data/document is available

Paramedical medical students, anesthesia residents

Under which criteria data/document could be used

for research and cite it

From where data/document is obtainable

h.faresani@gmail.com

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

It will be delivered within 10 days by sending an email

Comments