

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Comparison of the effectiveness of Magnesium Sulfate and Ketamine gargle on postoperative sore throat in patient with prone position during Laminectomy surgery.

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

The effect of Magnesium Sulfate and Ketamine gargle on postoperative sore throat

Design

Patient candidate for Laminectomy surgery randomly and with using table of random number divided in 3 groups and each group contain 20 individuals. Groups; Ketamine group, Magnesium Sulfate group and control's group. Sample size 60 was determined that divided in 3 groups. Clinical trial, single blind, with control group.

Settings and conduct

Patients candidate for Laminectomy surgery in Shohadaye Tajrish hospital divided in groups and participants have no information about groups and receiving medication or placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients between 30-70 years old candidate for Laminectomy surgery
Exclusion criteria: History of Hypertension or cardiac disease
Upper Respiratory Airway Infection
Cleft lip or palate
Arrhythmia
Cardiac conduction disorder

Intervention groups

Three groups; The first group gargles ketamine with 5% Dextrose serum and the second group Magnesium Sulfate plus 5% Dextrose and the third group (control) gargles 5% Dextrose as placebo.

Main outcome variables

The effect of Magnesium Sulfate and Ketamine gargle on postoperative sore throat.

Last update: **2020-02-14, 1398/11/25**

Update count: **0**

Registration date

2020-02-14, 1398/11/25

Registrant information

Name

Nima saeedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2641 8939

Email address

nimasaeedi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-15, 1398/10/25

Expected recruitment end date

2020-04-13, 1399/01/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Magnesium Sulfate and Ketamine gargle on postoperative sore throat in patient with prone position during Laminectomy surgery.

Public title

The effect of Magnesium Sulfate and Ketamine gargle on

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190131042569N2**

Registration date: **2020-02-14, 1398/11/25**

postoperative sore throat in patient with prone position.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All patients between 30-70 years old candidate for Laminectomy surgery

Exclusion criteria:

History of Hypertension or cardiac disease
Upper Respiratory Airway Infection
Cleft lip or palate
Arrhythmia
Cardiac conduction disorder

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Each patient who qualify for inclusion after completing the consent form is assigned by the person in charge of this process using a random number table from 1 to 60(1- 20 Ketamine group, 21-40 Magnesium Sulfate group, 41-60 control group) where the person is placed on one of the numbers and assigned to one of the 3 specified groups. (Simple randomization by individual using random number table).

Blinding (investigator's opinion)

Single blinded

Blinding description

The anesthesiologist in charge of anesthesia is not aware of the patient's group (intervention or control groups) whom receive anesthesia. And the person responsible for follow-up and recordings data and pain levels has no information about the intervention or control group and only one person responsible for giving the patient's drug or placebo is aware of the patient groups.

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee 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

1985717443

Approval date

2020-01-12, 1398/10/22

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.599

Health conditions studied

1

Description of health condition studied

Throat pain after intubation

ICD-10 code

R07.0

ICD-10 code description

Pain in throat

Primary outcomes

1

Description

Post operation throat pain

Timepoint

Upon arrival to recovery, 2,12 and 24 hours after surgery.

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Ketamine group: 1 mg/kg ketamine(Rotexmedica company) plus 30cc dextrose 5% gargled by patient for 30 seconds 15 minutes before induction.

Category

Prevention

2

Description

Intervention group2: Magnesium sulfate group: 30 mg/kg Magnesium sulfate(Pasteur Institute) plus 30cc dextrose 5% gargled by patient for 30 seconds 15 minutes before induction.

Category

Prevention

3

Description

Control group: 30cc dextrose 5% gargled by patient for 30 seconds 15 minutes before induction.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Nima Saeedi

Street address

Shohadaye Tajrish Hospital , Tajrish Square

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pr_shohada@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Department of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ali Ziayi

Street address

Third floor, School of Medicine, near the Taleghani Hospital, Evin, Shahid Chamran Highway

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1985717434

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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

Research Department of 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

Nima Saeedi

Position

Anesthesia assistance

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Name of organization / entity

Shahid Beheshti University of Medical Sciences

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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

Participant data (age, pain severity and type of patient's group) are to be shared.

When the data will become available and for how long

1 year after publication

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Using data and analysis for use in academic research

From where data/document is obtainable

Send Email Dr.Nima Saeedi Email Address:
nimasaeedi7@yahoo.com

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

Send request via Email and after 1 week will be replied.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nima Saeedi

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