

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The Effect of Magnesium Sulfate in Prevention of Sore Throat after Surgery in Patients Undergoing Endoscopic Sinus Surgery

Protocol summary

Study aim

The effect of magnesium sulfate on the prevention of postoperative sore throat in patients undergoing FESS

Design

In this study, 90 patients undergoing simple randomized endoscopic sinus surgery were enrolled in a double-blind clinical trial with 45 parallel groups.

Settings and conduct

This study was performed at Imam Khomeini Hospital in Ahvaz. The syringes are pre-prepared, numbered, and coated by an anesthetic technician who has not been involved in the study for blindness. To be a double-blind study, the designer, patient, and registrant of the results will be unaware of the type of injection solution. In recovery, 2, 6, and 12 hours later, the severity of the sore throat (based on the 0-10 criterion) and the incidence of cough is recorded.

Participants/Inclusion and exclusion criteria

Patient aged 18 to 60 years Class I and II by Classification of American Anesthesiology No pre-operative sore throat Upper airway infectious disease, Not having a cold, Not a smoker, No liver or kidney failure, Not to be pregnant, Magnesium insensitivity, Should not have been attempted for endotracheal intubation more than once, Not being in grade 3 or more, No chronic use of calcium blockers or magnesium

Intervention groups

The patient under general anesthesia will be injected with fentanyl 2µg/kg, midazolam 0.02 mg/kg and propofol 2mg/kg and to facilitate intratracheal endotracheal intubation 0.5 mg / kg. Atracurium 0.15 mg / kg is used to continue muscle relaxation if the patient returns. The laryngoscopy will be performed by an anesthesiologist with a metallic laryngoscope No. 3-4. Male patients with endotracheal tube with an inner diameter of 8 and female patients with with an inner diameter of 7.5 mm will be intubated. After intubation, 40 mg / kg magnesium sulfate is injected for 20 minutes at the same volume of normal saline for the control

group.

Main outcome variables

Sore throat Cough

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191030045272N1**

Registration date: **2019-11-11, 1398/08/20**

Registration timing: **retrospective**

Last update: **2019-11-11, 1398/08/20**

Update count: **0**

Registration date

2019-11-11, 1398/08/20

Registrant information

Name

Sara Adarvishi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3377 7966

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

2017-05-22, 1396/03/01

Actual recruitment end date

2019-03-11, 1397/12/20
Trial completion date
 2019-03-16, 1397/12/25

Scientific title
 The Effect of Magnesium Sulfate in Prevention of Sore Throat after Surgery in Patients Undergoing Endoscopic Sinus Surgery

Public title
 The Effect of Magnesium Sulfate in Prevention of Sore Throat after Surgery

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 They were classified Class I and II according to the American Anesthesia Association. To undergo FESS surgery at Imam Khomeini Hospital in Ahwaz in 1997-96.
Exclusion criteria:
 Consume calcium blockers or magnesium chronically. Malampati have grade 3 and above. Endotracheal intubation has been attempted more than once. Allergic to magnesium. To be pregnant. Have liver and kidney failure. To be smokers. They are cold. Have upper airway infectious disease. Have a history of pre-operative sore throat.

Age
 From **18 years** old to **60 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
 Target sample size: **90**
 Actual sample size reached: **90**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Patients who are candidates for endoscopic sinus surgery will be selected by census according to inclusion criteria and will be randomly treated using packages containing code A (magnesium) and B (placebo)

Blinding (investigator's opinion)
 Double blinded

Blinding description
 To be a double-blind study, the designer, patient, and registrant of the results will be unaware of the type of injection solution. The syringes are pre-prepared, numbered, and coated by an anesthetist who was not involved in the study.

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of ahvaz jundishapur University of Medical Sciences

Street address

Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd., Ahvaz

City

ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2018-02-03, 1396/11/14

Ethics committee reference number

IR.AJUMS.REC.1396.946

Health conditions studied

1

Description of health condition studied

Sore throat

ICD-10 code

J02.9

ICD-10 code description

Acute pharyngitis, unspecified

Primary outcomes

1

Description

Sore throat

Timepoint

In the post-anesthesia care unit and after full consciousness

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description

Cough

Timepoint

In recovery, 2, 6 and 12 hours after surgery

Method of measurement

observation

Intervention groups

1

Description

Intervention group: After intubation, 40 mg / kg magnesium sulfate is injected for 20 minutes.

Category

Prevention

2

Description

Control group: After intubation patients will be given normal saline for 20 minutes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khomeini Hospital

Full name of responsible person

Ahmadreza Mohtadi

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Khomeini Hospital, Shahid Ahvazian St., Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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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

Vice Chancellor for Research of Ahvaz Jundishapur 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

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammadreza Shafaf

Position

Associate Professor

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable