

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of pre-anesthesia and pre-intubation prescription of nebulized magnesium sulfate and dexamethasone on the incidence and severity of post extubation sore throat in patients under general anesthesia.

Protocol summary

Study aim

Comparison of pre-anesthesia and pre-intubation prescription of nebulized magnesium sulfate and dexamethasone on the incidence and severity of post extubation sore throat

Design

Double blinded randomized clinical trial. Patients will be randomly assigned to one of the three groups based on a randomization table. The patient and the person who is involved in the preparation of Nebulizers, as well as the person responsible for data collection are not aware of the study groups. The trial phase of the study is also 2-3.

Settings and conduct

Three hundred (300) patients in the operating room of Shahid Faghihi Hospital are divided into three groups including Dexamethasone group, magnesium sulfate nebulizer group and normal nebulizer group. The patient and the person who is involved in the preparation of the Nebulizers, as well as the person responsible for data collection are not aware of the type of intervention receiving by each study group.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients undergoing general anesthesia with endotracheal intubation, Aged 20 to 65 years, ASA I-II. Non-inclusion criteria: Sore throat, Upper respiratory tract infection, Using corticosteroids and calcium channel blockers, Allergy to the magnesium sulfate.

Intervention groups

The intervention group A consists of patients receiving 10 mg 8 mg dexamethasone nebuliser in 100 ml of normal saline for 5 minutes before the induction. The intervention group B consists of patients who receive magnesium sulfate nebulizer (30 mg per kg body weight) in 100 ml of normal saline for 10 minutes before the induction. Patients in the C group will receive normal

saline for five minutes before the induction.

Main outcome variables

Post extubation sore throat, Duration of intubation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N86**

Registration date: **2019-08-26, 1398/06/04**

Registration timing: **prospective**

Last update: **2019-08-26, 1398/06/04**

Update count: **0**

Registration date

2019-08-26, 1398/06/04

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-06, 1398/06/15

Expected recruitment end date

2019-11-17, 1398/08/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pre-anesthesia and pre-intubation prescription of nebulized magnesium sulfate and dexamethasone on the incidence and severity of post extubation sore throat in patients under general anesthesia.

Public title

The effect of nebulization on incidence and severity of sore throat after general anesthesia.

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients undergoing general anesthesia with endotracheal intubation Aged 20 to 65 years, ASA I-II

Exclusion criteria:

Sore throat, Upper respiratory tract infection, Using corticosteroids and calcium channel blockers Allergy to the magnesium sulfate Difficult intubation prediction Mallampati 3 and 4 Abnormalities in the face or mouth opening less than 40 mm More than once the attempt for intubation Kidney dysfunction, Diabetes mellitus Immunologic diseases, Prone and lateral position, The manipulation of the patient's throat during surgery by the surgeon Requiring the insertion of throat pack of , Placement of naso- gastric tube

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to one of the three groups based on a table which is derived from randomization.com site and the study will be started.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and the person who is involved in the preparation of the Nebulizers, as well as the person responsible for data collection are not aware of the type of intervention receiving by each study group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2017-07-25, 1396/05/03

Ethics committee reference number

IR.SUMS.MED.REC.1396.120

Health conditions studied**1****Description of health condition studied**

post extubation sore throat

ICD-10 code

R07.0

ICD-10 code description

Pain in throat

Primary outcomes**1****Description**

Post extubation sore throat

Timepoint

2 and 8 hours after extubation in the ward

Method of measurement

Visual Analog Scale

Secondary outcomes**1****Description**

Duration of intubation

Timepoint

Onset of intubation until the the extubation

Method of measurement

Observation

Intervention groups**1****Description**

Intervention group: The intervention group A consists of patients receiving 10 mg 8 mg dexamethasone nebuliser in 100 ml of normal saline for 5 minutes before the induction.

Category

Prevention

2**Description**

Intervention group: The intervention group B consists of patients who receive magnesium sulfate nebulizer (30 mg per kg body weight) in 100 ml of normal saline for 10 minutes before the induction.

Category

Prevention

3**Description**

Control group: Patients in the C group will receive normal saline for five minutes before the induction.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Faghihi Hospital

Full name of responsible person

Parisa Arab

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Faghihi Hospital, Zand boulevard

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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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

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Parisa Arab

Position

Anesthesiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mehrdad Salari

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Masihi

Position

BS in anesthesia/English Consultant

Latest degree

Master

Other areas of specialty/work

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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

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