

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 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

**Street address**

Faghihi Hospital, Zand boulevard

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namazi@sums.ac.ir

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

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Younes Ghasemi

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

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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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Anesthesiology Department, Faghihi Hospital, Zand Street

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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

**Position**

Anesthesiologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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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**

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**

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