Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 endotrachial 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

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Iran (Islamic Republic of)

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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 endotrachial 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Person responsible for updating data

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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