

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the effect of licorice extract, ketamine and magnesium sulfate on gargling before laryngoscopy and endotracheal intubation in the prevention of sore throat, hoarseness and cough

Protocol summary

Study aim

Evaluation effect of licorice extract, ketamine and magnesium sulfate on gargling before laryngoscopy and endotracheal intubation in the prevention of sore throat, hoarseness and cough

Design

The study will be double blind and clinical trial. 105 patients will be randomly divided into 3 groups. The groups are parallel. The trial phase is 3

Settings and conduct

Patients candidate for general anesthesia in valiasr Hospital in Arak are divided into 3 groups by simple randomization with blocks. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: no history of drug use; no upper airway infection and cold; no mallampati more than 2; lack of liver and kidney failure; no need to use NG-tube during surgery and up to 24 hours after surgery; the duration of surgery should not be less than 45 minutes and not more than 120 minutes Exclusion criteria: Patient dissatisfaction to continue attending the study; observing blood during suctioning when the endotracheal tube is removed; for any reason, we have to do laryngoscopy twice in the patient; history of heart disease and high blood pressure

Intervention groups

First intervention group: 0.5 milligram in kilogram Ketamine with 100 milligram of lidocaine and 10 millilitre of 20% dextrose will gargle. Second intervention group: 0.5 gram (500 milligram) licorice powder dissolved in distilled water by volume (5 millilitre) with 100 milligram lidocaine and 10 ml dextrose 20% gargle Will do. Third intervention group: 2 gram of magnesium sulfate along with 100 milligram of lidocaine and 10 millilitre of dextrose will gargle 20%.

Main outcome variables

Sore throat, cough, hoarseness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N170**

Registration date: **2021-12-18, 1400/09/27**

Registration timing: **prospective**

Last update: **2021-12-18, 1400/09/27**

Update count: **0**

Registration date

2021-12-18, 1400/09/27

Registrant information

Name

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Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15

Expected recruitment end date

2023-01-05, 1401/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of licorice extract, ketamine and magnesium sulfate on gargling before laryngoscopy and endotracheal intubation in the prevention of sore throat, hoarseness and cough

Public title

Comparison of the effect of licorice extract, ketamine and magnesium sulfate on gargling before laryngoscopy and endotracheal intubation in the prevention of sore throat, hoarseness and cough

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

30 to 60 years ASA class I and II No history of sore throat before surgery No history of head and neck surgery, especially throat No history of drug use No history of chronic housing use Hypersensitivity to the drugs used in this study No upper airway infection and cold No mallampati more than 2 Lack of liver and kidney failure No need to use NG-tube during surgery and up to 24 hours after surgery The duration of surgery should not be less than 45 minutes and not more than 120 minutes

Exclusion criteria:

Patient dissatisfaction to continue attending the study Observing blood during suctioning when the endotracheal tube is removed For any reason, we have to do laryngoscopy twice in the patient History of heart disease and high blood pressure

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated into 3 groups using a permuted balanced block randomization method with the size of blocks 3 and 6. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Random chain concealment is done by opaque envelope method.

Blinding (investigator's opinion)

Double blinded

Blinding description

It is a double-blind study. Analysts, evaluators, and

participants are unaware of the grouping. The intern is unaware of the drugs prescribed in each group and the anesthesiologist prepares the drugs and provides them to the intern, and the patients are not aware of their group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak

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Approval date

2021-09-29, 1400/07/07

Ethics committee reference number

IR.ARAKMU.REC.1400.167

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

General anesthesia

ICD-10 code

T88.5

ICD-10 code description

Other complications of anaesthesia

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

Sore throat

Timepoint

In recovery, 2, 4, 8, 12 and 24 hours after surgery

Method of measurement

Visual Pain Questionnaire

2**Description**

Cough

Timepoint

In recovery, 2, 4, 8, 12 and 24 hours after surgery

Method of measurement

Physical examination

3**Description**

hoarseness

Timepoint

In recovery, 2, 4, 8, 12 and 24 hours after surgery

Method of measurement

Physical examination

Secondary outcomes

empty

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

First intervention group: 0.5 milligram in kilogram Ketamine German company Rotex Medica, importer of Pan Pharma Therapeutic Drug Finder) with 100 milligram of lidocaine (Caspian Tamin Rasht - Iran) and 10 milliliter of 20% dextrose (Shahid Ghazi Pharmaceutical Company - Tabriz) will gargle.

Category

Treatment - Drugs

2**Description**

Second intervention group: 0.5 geram (500 milligram)licorice powder dissolved in distilled water by volume (5 millilitre) with 100 milligram lidocaine and 10 ml dextrose 20% gargle Will do.

Category

Treatment - Drugs

3**Description**

Third intervention group: 2 gram of magnesium sulfate (50% made by Shahid Ghazi Pharmaceutical Company - Iran Tabriz) along with 100 milligram of lidocaine and 10 milliliter of dextrose will gargle 20%.

Category

Treatment - Drugs

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

Valiasr hospital

Full name of responsible person

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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

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Dr Behnam Mahmodie

Position

Associate professor

Latest degree

Specialist

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