Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 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. 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
Fariba Farokhi

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 comittee of Arak University of Medical Sciences
Street address
Ethics comittee, Research center, Payambar Azam complex, Basij squre ,Sardasht,Arak
City
Arak
Province
Markazi
Postal code
3848176941
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
Dr Hesamodin Modir
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Valiasr hospital, Valiasr squre
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Sponsors / Funding sources

1

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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