Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of gargling rosemary extract and Ketamine on hoarseness and sore throat after tracheal intubation

Protocol summary

Study aim
Investigating the effect of rosemary gargle and ketamine on sore throat and hoarseness after tracheal intubation

Design
A controlled, parallel-group, triple-blind, randomized, phase 2 clinical trial on 120 patients.

Settings and conduct
This is a three-blind randomized clinical trial that will be conducted on 120 general anesthesia candidates undergoing tracheal intubation in Al-Zahra Hospital, Isfahan. After the approval of the ethics committee of the university and obtaining the consent of the patients, the patients are randomly assigned into groups, in each group the desired intervention is applied and the clinical symptoms of the patient are recorded. The researcher who records the patient's symptoms, the analysts who collect the data analyzed during the study, and the patients did not know the type of intervention applied in each group, so they were all blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18 to 65 years, ASA anesthesia class I and II, candidate for general anesthesia under tracheal intubation, and consent to participate in the study.Exclusion criteria: smoking and drug addiction, allergy to used drugs, diabetes, asthma and airway problems

Intervention groups
Intervention group A: In this group, patients gargle 30 drops of rosemary solution (manufactured by Fadak Sepahan Pharmaceutical Company) dissolved in 30 ml of distilled water for 2-3 minutes before induction of anesthesia. Intervention group B: In this group, patients gargle 40 mg of Ketamine dissolved in 30 ml of distilled water for 30 seconds before induction of anesthesia. Intervention group C: In this group, patients gargle 30 ml of distilled water for 2-3 minutes before induction of anesthesia.

Main outcome variables
Sore throat, Hoarseness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160307026950N50**
Registration date: **2023-01-01, 1401/10/11**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-01, 1401/10/11**
Update count: **0**

Registration date
2023-01-01, 1401/10/11

Registrant information

Name
Behzad Nazemroaya

Name of organization / entity
Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

Expected recruitment end date
2023-02-20, 1401/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of gargling rosemary extract and Ketamine on hoarseness and sore throat after tracheal intubation

Public title
Effect of gargling rosemary extract and Ketamine on hoarseness and sore throat
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients 18 to 65 years old Anesthesia class I and II according to ASA criteria Candidate for general anesthesia with tracheal intubation Informed consent to enter the study
Exclusion criteria:
Addiction to cigarettes and drugs Allergic to rosemary and Ketamine Diabetes Asthma and airway problems
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done in a simple way so that the patients are entered into groups A, B, and C according to the time of their arrival in the operating room, and this will continue until the number of patients in each group reaches 40 people.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This is a three-way blind clinical trial; In this way, the researcher who records the patient's symptoms is different from the person who prescribes the drug and has no knowledge of the type of drug and is blind. The analysts who analyze the data collected during the study also know the type of intervention. They don't have it in any group and they are blind. Even though the patients are included in the study, they do not know the type of intervention and are blind.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Biomedical Research, Isfahan University of Medical Sciences
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Hezar Jarib
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Isfehan
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8174673461
Approval date
2022-05-15, 1401/02/25
Ethics committee reference number
IR.MUI.MED.REC.1401.056

Health conditions studied

1

Description of health condition studied
Sore throat and Hoarseness after endotracheal intubation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Severity of sore throat
Timepoint
1 hour after recovery and 6, 12, 24 and 48 hours after that
Method of measurement
Scoring from 0 to 10 based on pain intensity

2

Description
Severity of hoarseness
Timepoint
1 hour after recovery and 6, 12, 24 and 48 hours after that
Method of measurement
Scoring from 0 to 3 based on the severity of hoarseness

Secondary outcomes

1

Description
Blood Pressure
Timepoint
From the time of induction of anesthesia until the end of

recovery

Method of measurement

sphygmomanometer

2

Description

Heart Rate

Timepoint

From the time of induction of anesthesia until the end of recovery

Method of measurement

Electrocardiogram

Intervention groups

1

Description

Intervention group A: In this group of patients, before induction of anesthesia, 30 drops of Rosemary solution (manufactured by Fadek Sepahan Pharmaceutical Company) dissolved in 30 ml of distilled water are gargled for 2-3 minutes, then 5 mg/kg Thiopental is administered to induce anesthesia. Sodium manufactured by Elixir Pharmaceutical Company, 100 Micrograms of fentanyl manufactured by Caspin Pharmaceutical Company, and 0.5 mg/kg of Atracurium manufactured by Aburihan Pharmaceutical Company is injected. Sampling and recording of symptoms are also done during and after anesthesia.

Category

Prevention

2

Description

Intervention group B: In this group, patients gargle 40 mg of Ketamine dissolved in 30 ml of distilled water for 30 seconds before induction of anesthesia, then 5 mg/kg Thiopental is administered to induce anesthesia. Sodium manufactured by Elixir Pharmaceutical Company, 100 Micrograms of fentanyl manufactured by Caspin Pharmaceutical Company, and 0.5 mg/kg of Atracurium manufactured by Aburihan Pharmaceutical Company is injected. Sampling and recording of symptoms are also done during and after anesthesia.

Category

Prevention

3

Description

Control group C: In this group, patients gargle 30 ml of distilled water for 2-3 minutes before induction of anesthesia, then 5 mg/kg Thiopental is administered to induce anesthesia. Sodium manufactured by Elixir Pharmaceutical Company, 100 Micrograms of fentanyl manufactured by Caspin Pharmaceutical Company, and 0.5 mg/kg of Atracurium manufactured by Aburihan Pharmaceutical Company is injected. Sampling and recording of symptoms are also done during and after anesthesia.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra 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

Esfahan 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
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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