Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

Country
Iran (Islamic Republic of)

Phone
+98 31 3212 3543

Email address
behzad_nazem@med.mui.ac.ir

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

Street address
Hezar Jarib

City
Isfahan

Province
Isfehan

Postal code
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

Behzad Nazemroaya

Street address

Soffeh boulevard, Shahid Keshvari highway

City

Isfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

behzad_nazem@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Hezar Jarib

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

research@mui.ac.ir

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
Esfahan University of Medical Sciences
Full name of responsible person
Roza Bidkalameh
Position
Medical student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Hezar Jarib
City
Isfahan
Province
Isfehan
Postal code
8146713543
Phone
+98 31 3620 2020
Email
rozabidkalame94@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Behzad Nazem roaya
Position
Professor assistant of Anesthesia and Intensive care
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Hezar Jarib
City
Isfahan
Province
Isfehan
Postal code
8146713543
Phone
+98 31 3620 2020
Email
behzad_nazem@med.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Leyla Rafiei
Position
Nurse Anesthetist
Latest degree
Bachelor
Other areas of specialty/work
Anesthesiology
Street address
Hezar Jarib
City
Isfahan
Province
Isfehan
Postal code
8146713543
Phone
+98 31 3620 2020
Email
Leylarafiei943@gmail.com

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