Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the Effectiveness of Ginger Tea Gargling with Ketamine Gargling in Preventing Postoperative Sore Throat in Patients Under General Anesthesia with Endotracheal Intubation

Protocol summary

Study aim

To compare the effectiveness of ginger tea gargle and ketamine gargle in preventing and reducing the severity of postoperative sore throat in patients undergoing general anesthesia with endotracheal intubation. Secondary objectives: To compare the severity of postoperative sore throat. To compare the incidence of postoperative sore throat among the study groups.

Design

A randomized, controlled, double-blind, three-arm parallel clinical trial will be conducted in patients undergoing elective surgery. Participants will be randomly allocated to ginger tea gargle, ketamine gargle, and control groups using block randomization with a block size of six. The study will include 150 participants. This trial will be conducted as a phase 3 clinical trial.

Settings and conduct

Patients undergoing elective surgery under general anesthesia with endotracheal intubation will be randomly assigned to three groups (ginger, ketamine, and control) after informed consent. The solutions will be prepared in coded bottles, and participants and outcome assessors will be blinded to group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing elective surgery under general anesthesia requiring endotracheal intubation for more than 30 minutes. (ASA) physical status I–II. provision of written informed consent. Exclusion criteria: History of allergy to ginger or ketamine. presence of underlying throat-related conditions. emergency surgery. body mass index (BMI) >35 kg/m². operative duration exceeding 3 hours.

Intervention groups

ginger tea gargle group, ketamine gargle group, and control group

Main outcome variables

Incidence of postoperative sore throat; severity of postoperative sore throat at different assessment time points; comparison of the effectiveness of ginger tea gargle and ketamine gargle in reducing sore throat after endotracheal intubation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N85**
Registration date: **2026-08-01, 1405/05/10**
Registration timing: **prospective**

Last update: **2026-08-01, 1405/05/10**
Update count: **0**

Registration date

2026-08-01, 1405/05/10

Registrant information

Name
Behzad Nazemroaya
Name of organization / entity
Isfahan University of Medical Sciences
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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-23, 1405/07/01

Expected recruitment end date

2027-05-22, 1406/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effectiveness of Ginger Tea Gargling with Ketamine Gargling in Preventing Postoperative Sore Throat in Patients Under General Anesthesia with Endotracheal Intubation

Public title

Comparison of Preventive Strategies for Postoperative Sore Throat

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Written informed consent obtained absence of underlying throat-related conditions (e.g., severe gastroesophageal reflux disease [GERD] or respiratory tract infection) Patients with American Society of Anesthesiologists (ASA) physical status I–II Patients undergoing elective surgical procedures (e.g., cholecystectomy, hernia repair, or thyroidectomy) requiring endotracheal intubation for a duration exceeding 30 minutes

Exclusion criteria:

Allergy to ginger or ketamine emergency surgery body mass index (BMI) >35 kg/m² surgery lasting more than 3 hours

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation sequence will be generated using block randomization with a fixed block size of 6, with an allocation ratio of 1:1:1 to the ginger, ketamine, and control groups. The randomization sequence will be generated using the online Sealed Envelope Randomization Service. The generated sequence will be used sequentially for participant allocation. The randomization list will be prepared and maintained by an individual independent of the outcome assessors, and group allocation will remain concealed from the patients and outcome assessors until completion of the intervention and outcome assessment.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be conducted using a double-blind design. Participants will be blinded to the type of intervention received (ginger tea gargle, ketamine gargle, or control solution). All solutions will be prepared by the hospital pharmacist in identical, coded bottles to ensure that the interventions are indistinguishable. Outcome assessors (recovery room nurses or interns) responsible for evaluating postoperative sore throat will be blinded to group allocation. Healthcare personnel involved in routine postoperative care will remain unaware of treatment allocation whenever they do not require access to the randomization codes. The principal investigator and research team members involved in data collection and analysis will not have access to the allocation codes until completion of data collection and initial analyses. The randomization codes will be revealed only after completion of the planned analyses. Data analysts will analyze coded data without knowledge of intervention assignments whenever feasible. Members of the Data Safety Monitoring Committee (if applicable) and individuals involved in manuscript preparation will remain blinded to group allocation unless access to this information is required.

Placebo

Used

Assignment

Parallel

Other design features

This study is designed as a prospective, randomized, controlled, double-blind, three-arm parallel clinical trial. Participants will be randomly allocated to three parallel groups using block randomization with a block size of six: ginger tea gargle, ketamine gargle, and control groups. To maintain blinding, all solutions will be prepared by the hospital pharmacist in identical, coded bottles. Participants and outcome assessors (recovery room nurses or interns) will be blinded to group allocation. The incidence and severity of postoperative sore throat following endotracheal intubation will be assessed at predefined time points and compared among the groups

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib street, Azadi square, Isfahan

City

Isfahan

Province

Isfehan

Postal code
8174673461
Approval date
2026-07-08, 1405/04/17
Ethics committee reference number
IR.MUI.MED.REC.1405.154

Health conditions studied

1

Description of health condition studied
sore throat
ICD-10 code
R07.0
ICD-10 code description
Pain in throat

Primary outcomes

1

Description
Severity of postoperative sore throat (POST) following endotracheal intubation, measured using the visual analog scale (VAS: 0–10)
Timepoint
Assessment of postoperative sore throat (POST) severity using the visual analog scale (VAS: 0–10) at 2, 6, and 24 hours after surgery.
Method of measurement
Visual Analogue Scale for assessment of postoperative sore throat severity, consisting of a 10-centimeter line scored from zero (no sore throat) to 10 (the worst imaginable sore throat).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receiving ginger tea gargle solution according to the study protocol before surgery; the solution is prepared in identical coded bottles and administered by gargling.
Category
Prevention

2

Description
Intervention group: Receiving ketamine gargle solution according to the study protocol before surgery; the solution is prepared in identical coded bottles and administered by gargling.
Category
Prevention

3

Description
Control group: Receiving a control solution (placebo) similar to the intervention solutions, without the active ingredient, prepared in identical coded bottles; administered according to the study protocol before surgery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahara 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?
No
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
Behzad Nazemroaya

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The main outcome information will be shared after being de-identified

When the data will become available and for how long
Access period begins 6 months after results are published

To whom data/document is available
Employees in public and private scientific institutions

Under which criteria data/document could be used
Analysis on the data is not allowed

From where data/document is obtainable

Behzad Nazim Al-Raaya with email behzad_nazem@med.mui.ac.ir

What processes are involved for a request to access data/document

Immediately upon request

Comments