

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Country

Iran (Islamic Republic of)

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Recruitment status

Not yet 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

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Province

Isfahan

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

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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
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Full name of responsible person
Behzad Nazemroaya
Position
Associate Professor
Latest degree
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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
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What processes are involved for a request to access

data/document
Immediately upon request
Comments