

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of frequency of post operative sore throat in patients undergoing oral endotracheal intubation with ketamine gargles and normal saline

Protocol summary

Study aim

To compare the effectiveness of ketamine gargles versus normal saline gargles in reducing the incidence and severity of postoperative sore throat in adult patients undergoing oral endotracheal intubation for surgery under general anesthesia.

Design

Single-blind, parallel-group, non-randomized controlled trial conducted at a single tertiary care center. A total of 156 adult patients were allocated to either a ketamine gargle or a normal saline gargle groups and post operative sore throat was assessed using a 4-point grading scale at 0,2,4,8,24 hours post operatively.

Settings and conduct

The study was conducted in the Department of Anesthesiology, Lady Reading Hospital, Peshawar, Pakistan. Eligible patients undergoing surgery under general anesthesia with oral endotracheal intubation were enrolled after informed consent and followed according to the study protocol.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male and female patients aged 18 to 70 years undergoing oral endotracheal intubation under general anesthesia. Exclusion criteria: Patients with upper respiratory tract infection, preoperative sore throat, known hypersensitivity to ketamine, or inability to perform gargling, having NG tube

Intervention groups

Intervention group (Ketamine group): Participants received ketamine gargles containing 50 mg ketamine diluted in 29 mL water and gargled for 40 seconds before induction of general anesthesia. (Control group): Participants received normal saline gargles of equal volume and gargled for 40 seconds before induction of general anesthesia. Postoperative sore throat was assessed using a 4-point grading scale at 0,2,4,8,24 hours postoperatively.

Main outcome variables

Postoperative sore throat incidence and severity measured at 0,2,8 and 24 hours after extubation

General information

Reason for update

Acronym

KGPOST

IRCT registration information

IRCT registration number: **IRCT20260611069751N1**

Registration date: **2026-06-23, 1405/04/02**

Registration timing: **retrospective**

Last update: **2026-06-23, 1405/04/02**

Update count: **0**

Registration date

2026-06-23, 1405/04/02

Registrant information

Name

Saima Askar Bangash

Name of organization / entity

Lady reading hospital

Country

Pakistan

Phone

+92 91 9211430

Email address

docseeme@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-18, 1404/07/26

Expected recruitment end date

2026-05-22, 1405/03/01

Actual recruitment start date

2025-10-18, 1404/07/26

Actual recruitment end date

2026-05-22, 1405/03/01

Trial completion date

2026-05-23, 1405/03/02

Scientific title

Comparison of frequency of post operative sore throat in patients undergoing oral endotracheal intubation with ketamine gargles and normal saline

Public title

Effect of Ketamine gargles on sore throat after surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient gender male-female Patient age (18-70) Years Patients undergoing oral endotracheal intubation as per operational definition ASA physical status I or II Provided written informed consent

Exclusion criteria:

Known case of allergies to ketamine Upper respiratory tract infection Pre existing throat pathology Refusal to participate More than one intubation attempt Those having ng tube already placed

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **156**

Actual sample size reached: **156**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

Participants were blinded to the allocated intervention. Patients were not informed whether they received ketamine gargles or normal saline gargles. The investigators and care providers were aware of the allocated intervention. Therefore, the study was conducted as a single-blind trial with participant blinding only.

Placebo

Used

Assignment

Parallel

Other design features

Single-blind, parallel-group interventional study. Participants were blinded to treatment allocation. Patients received either ketamine gargles or normal saline gargles on alternate study days. Investigators and care providers were aware of group allocation.

Postoperative sore throat was assessed after oral endotracheal intubation.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Institutional Review Board (IRB), Lady Reading Hospital Medical Teaching Institution(LRH-MTI)

Street address

Research Cell, 4th floor, MedSurge Block, Lady Reading Hospital, Peshawar, Kpk, Pakistan

City

Peshawar

Postal code

25000

Approval date

2024-10-31, 1403/08/10

Ethics committee reference number

430/LRH/MTI

Health conditions studied**1****Description of health condition studied**

Postoperative sore throat following oral endotracheal intubation

ICD-10 code

R07.0

ICD-10 code description

Pain in throat

Primary outcomes**1****Description**

Frequency of postoperative sore throat following oral endotracheal intubation

Timepoint

0, 2, 4, 8 and 24 hours after extubation

Method of measurement

Postoperative sore throat was assessed by direct patient interview and graded using a standardized postoperative sore throat grading scale 0, 2, 4, 8 and 24 hours after extubation.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants received ketamine gargles containing 50mg ketamine diluted in 29ml water and gargled for 40 seconds before induction of general anesthesia.

Category

Treatment - Drugs

2

Description

Control group: Participants received normal saline gargles of equal volume and gargled for 40 seconds before induction of general anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Lady Reading Hospital Medical Teaching Institution(LRH-MTI)

Full name of responsible person

Saima Askar Bangash

Street address

Research cell, 4th floor, Medsurge Block, Lady Reading Hospital, Peshawar, Kpk, Pakistan

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Https://www.lrh.edu.pk

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Lady Reading Hospital Medical Teaching Institution (LRH-MTI)

Full name of responsible person

Saima Askar Bangash

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Grant name

Self-funded investigator initiated study

Grant code / Reference number

N/A

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Lady Reading Hospital Medical Teaching Institution (LRH-MTI)

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

Lady reading Hospital Medical Teaching Institution (LRH-MTI)

Full name of responsible person

Saima Askar Bangash

Position

Principal investigator

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Institution(LRH-MTI)

Full name of responsible person

Saima Askar Bangash

Position

Principal investigator

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Individual participant data will not be shared publicly to protect participant confidentiality and privacy .the study was conducted for academic purposes and no plan exists for public release of deidentified dataset.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Person responsible for updating data

Contact

Name of organization / entity

Lady reading hospital

Full name of responsible person

Saima Askar Bangash

Position

Training medical officer

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology