Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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+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 24hours 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
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Sponsors / Funding sources

1

Sponsor
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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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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