Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A Randomized, Double-Blinded Comparative Study of Pre-Operative Nebulized Dexamethasone and Intravenous Ketorolac Tromethamine for the Prevention of Post-Operative Sore Throat Following General Anesthesia

Protocol summary

Study aim

• To assess the incidence and severity of postoperative sore throat (POST) in patients receiving preoperative nebulized dexamethasone and intravenous ketorolac. • To compare the anti-inflammatory effect of Steroid (Dexamethasone) versus non-steroid (Ketorolac tromethamine) in reducing POST.

Design

This study employed a randomized, double-blinded research design.

Settings and conduct

The study was be conducted at Farooq Hospital, DHA, specifically within the Department of Anesthesia.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Patients aged 18 – 50 undergoing surgeries that require endotracheal intubation after general anesthesia • ASA Physical status of I–III. • Patient giving informed consent. Exclusion criteria. • Patient known to be allergic to study drugs. • Asthmatic or COPD patients. • ASA physical status IV – VI • The Patient has a pre-existing sore throat or pain • Surgeries involving the neck, throat, or airway. • Upper respiratory tract infection. • Patients with a history of renal disease

Intervention groups

Interventions: Group K (Ketorolac group): Participants in this group will receive intravenous ketorolac tromethamine preoperatively, 15–30 minutes before induction of general anesthesia. Group D (Dexamethasone group): Participants in this group will receive nebulized dexamethasone preoperatively, 15–30 minutes before induction of general anesthesia.

Main outcome variables

Main Outcome Variables: Incidence of Postoperative Sore Throat (POST): Presence or absence of sore throat at 2, 4, 6, and 12 hours after extubation. Severity of Postoperative Sore Throat: Measured using the STAT-10 scale at 2, 4, 6, and 12 hours post-extubation. Anti-inflammatory Effect of Intervention: Assessed indirectly through reduction in sore throat severity scores between the two groups.

General information

Reason for update

Acronym

POST: Postoperative Sore Throat

IRCT registration information

IRCT registration number: **IRCT20260222068917N1**
Registration date: **2026-02-25, 1404/12/06**
Registration timing: **retrospective**

Last update: **2026-02-25, 1404/12/06**
Update count: **0**

Registration date

2026-02-25, 1404/12/06

Registrant information

Name
Abdul Mabood
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-16, 1404/04/25

Expected recruitment end date

2026-01-12, 1404/10/22

Actual recruitment start date

2025-07-16, 1404/04/25

Actual recruitment end date

2026-01-12, 1404/10/22

Trial completion date

2026-01-12, 1404/10/22

Scientific title

A Randomized, Double-Blinded Comparative Study of Pre-Operative Nebulized Dexamethasone and Intravenous Ketorolac Tromethamine for the Prevention of Post-Operative Sore Throat Following General Anesthesia

Public title

A Randomized, Double-Blinded Comparative Study of Pre-Operative Nebulized Dexamethasone and Intravenous Ketorolac Tromethamine for the Prevention of Post-Operative Sore Throat Following General Anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 18 – 50 undergoing surgeries that require endotracheal intubation after general anesthesia ASA Physical status of I–III Patient giving informed consent.

Exclusion criteria:

Patient known to be allergic to study drugs Asthmatic or COPD patients ASA physical status IV – VI The Patient has a pre-existing sore throat or pain Surgeries involving the neck, throat, or airway Upper respiratory tract infection Patients with a history of renal disease

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants in this study were allocated to either the pre-operative nebulized dexamethasone group or the intravenous ketorolac tromethamine group using simple randomization at the level of the individual participant. No stratified randomization was applied, as the study population was homogeneous regarding age, gender, and type of surgery. The random sequence was prepared manually using a table of random numbers, and each participant was assigned a unique sequential number upon enrollment, which was then matched to the pre-prepared random allocation list to determine group assignment. Allocation concealment was maintained using sealed opaque envelopes, which were opened only at the time of intervention to prevent selection bias. No pseudorandomization methods, such as odd/even days, birthdays, or physician choice, were used.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants are blinded to the type of intervention they receive, as both nebulized dexamethasone and intravenous ketorolac tromethamine are administered in a manner that conceals group allocation. The principal investigator and outcome assessors are also blinded to group assignments to prevent assessment bias when recording postoperative sore throat outcomes. Healthcare providers administering the interventions are aware of the treatment for practical reasons but do not participate in outcome assessment. Data collectors and individuals entering and analyzing the data are blinded to group allocation to maintain objectivity. A sealed opaque envelope system ensures that group allocation remains concealed until the intervention is given. The Data Safety and Monitoring Board (DSMB) and manuscript writers are not involved in treatment administration or outcome assessment and remain unaware of group assignments until study completion. This blinding strategy minimizes bias at multiple levels of the study while maintaining safety and practical feasibility.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Research Ethical Committee, Superior University, Lahore

Street address

17 Km Raiwind Road, Lahore, Pakistan

City

Lahore

Postal code

54000

Approval date

2025-10-16, 1404/07/24

Ethics committee reference number

IRB /FAHS/Allied/10/25/MS/AHS-3836

Health conditions studied

1

Description of health condition studied
Postoperative Sore Throat (POST) following General Anesthesia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Incidence and Severity of Postoperative Sore Throat (POST)
Timepoint
Measured at 2, 4, 6, and 12 hours after extubation
Method of measurement
Severity was assessed using the STAT-10 scale, a validated questionnaire for postoperative sore throat.Incidence is recorded as the presence or absence of sore throat at each time point

Secondary outcomes

1

Description
Timepoint
Method of measurement

2

Description
Secondary outcomes include intubation-related factors (number of attempts and their association with POST severity), cuff pressure categories (≤24 vs >24 cm H_2O), surgery-related factors (type and duration of surgery), endotracheal tube size, postoperative complications (nausea, vomiting, GI irritation, hyperglycemia, delayed wound healing, and others), and requirement for rescue analgesia
Timepoint
Secondary outcomes was measured at 2, 4, 6, and 12 hours after extubation for outcomes related to POST and complications
Method of measurement
The secondary outcomes are measured using a combination of direct observation, structured questionnaires, and patient records. Intubation attempts and endotracheal tube size are recorded intraoperatively from anesthesia notes. Cuff pressure is measured using a manometer at the time of intubation. Surgery type and duration are documented from operative records. Postoperative complications such as nausea, vomiting, GI irritation, hyperglycemia, delayed wound healing, and others are monitored through direct observation and patient self-report. Rescue analgesia requirement is recorded from patient charts and by direct inquiry during the 12-hour postoperative period. Outcome assessors are blinded to group allocation to minimize bias.

Intervention groups

1

Description
Intervention Group 1: Group D – Dexamethasone, Participants receive preoperative nebulized dexamethasone, 15–30 minutes before induction of general anesthesia.
Category
Treatment - Drugs

2

Description
Intervention group 2: Group K – Ketorolac, Participants receive intravenous ketorolac tromethamine, 15–30 minutes before induction of general anesthesia.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Farooq Hospital, DHA, Lahore
Full name of responsible person
Abdul Mabood
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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?
Yes
Title of funding source
Superior University, Lahore
Proportion provided by this source
100
Public or private sector
Private
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
Superior University, Lahore
Full name of responsible person
Abdul Mabood
Position
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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
There is no further information.
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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available