# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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**
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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**

**Sponsor**
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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
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Abdul Mabood
**Position**
MS Scholar
**Latest degree**
Master
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Anesthesiology
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## Person responsible for updating data

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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