

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of the Effect of Intravenous Hydrocortison Administration on post-Anesthesi General Sore Throat

Protocol summary

Study aim

To determine and compare the incidence and severity of post-anesthetic sore throat in the recovery room after full consciousness, as well as at 6 and 24 hours following extubation, between the intervention and control groups.

Design

This study will be conducted as a randomized double-blind clinical trial. The intervention group will receive intravenous hydrocortisone at a dose of 1.5 mg/kg before induction of anesthesia, while the control group will receive normal saline. The severity of postoperative sore throat will be assessed and recorded using the Visual Analog Scale (VAS) upon admission to the recovery room and at 6 and 24 hours after tracheal extubation.

Settings and conduct

A randomized double-blind parallel-group controlled clinical trial

Participants/Inclusion and exclusion criteria

participants: Patients scheduled for general anesthesia and endotracheal intubation. Inclusion criteria: Patient consent, age 18 to 65 years without underlying disease. Exclusion criteria: Hypersensitivity to hydrocortisone, difficulty in intubation, history of chronic sore throat, recent upper respiratory tract infection.

Intervention groups

Intervention group: Participants will receive intravenous hydrocortisone at a dose of 1.5 mg/kg diluted in a 10-cc syringe administered as an intravenous infusion over 10 minutes before induction of general anesthesia. Control group: Participants will receive 10 cc of normal saline administered as an intravenous infusion over 10 minutes before induction of general anesthesia.

Main outcome variables

Severity of postoperative sore throat measured using the Visual Analog Scale (VAS) upon admission to the recovery room and at 6 and 24 hours after tracheal extubation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251231068511N1**

Registration date: **2026-07-21, 1405/04/30**

Registration timing: **retrospective**

Last update: **2026-07-21, 1405/04/30**

Update count: **0**

Registration date

2026-07-21, 1405/04/30

Registrant information

Name

Sare Raeisi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3322 8409

Email address

sare4884@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-04, 1405/03/14

Expected recruitment end date

2026-07-20, 1405/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Intravenous Hydrocortison Administration on post-Anesthesi General Sore Throat	
Public title	Evaluation of The Effeect of Intravenous Hydrocortisone Administration on posst-Anesthesia General Sore Throat
Purpose	Prevention
Inclusion/Exclusion criteria	Inclusion criteria: The patient must be willing to participate in the study The patient must be between 18 and 65 years old no underlying condition The patient must be candidate for general anesthesia Exclusion criteria: Drug allergy to Hydrocortison Multipples attempts at intubation History of chronic sore throat History of recent Upper Respiratory Tract Infection
Age	From 18 years old to 65 years old
Gender	Both
Phase	3
Groups that have been masked	• Participant • Investigator • Outcome assessor
Sample size	Target sample size: 56
Randomization (investigator's opinion)	Randomized
Randomization description	Participants will be randomly assigned to the intervention or control group using simple randomization. Randomization will be performed using a random number table until the required sample size for each group is reached. Even numbers will be assigned to the hydrocortisone intervention group, and odd numbers will be assigned to the control group.
Blinding (investigator's opinion)	Double blinded
Blinding description	The study will be conducted as a double-blind trial, where both the participants and the outcome assessor are blinded to the treatment allocation. Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes (SNOSE). The randomization sequence will be generated first; then, the allocation will be written on a card and placed inside each envelope in the generated order. The envelopes will be numbered sequentially on the outside and placed in a box. Upon enrollment, each participant will receive the next available envelope in the sequence to determine their treatment assignment.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	1 Ethics committee Name of ethics committee Ethics Committee of Zahedan University of Medical Sciences Street address Persian Gulf Boulevard, Dr.Hesabi Square University of Medical Sciences Campus, Central Headquarters Building, Second Floor. City Zahedan Province Sistan-va-Balouchestan Postal code 9816743463 Approval date 2025-02-08, 1403/11/20 Ethics committee reference number IR.ZAUMS.REC.1403.450
Health conditions studied	1 Description of health condition studied Evaluation of the Effect of Intravenous Hydrocortisone Administration on Postoperative Sore Throat Following General Anesthesia ICD-10 code ICD-10 code description
Primary outcomes	1 Description Severity score of postoperative sore throat following tracheal extubation after general anesthesia Timepoint Assessment of postoperative sore throat severity upon admission to the recovery room ,and at 6 and 24 hours after tracheal extubation Method of measurement Based on the Visual Analogue Scale pain scale
Secondary outcomes	empty
Intervention groups	1 Description Intervantion group:Participants in this group will receive

intravenous hydrocortisone at a dose of 1.5 mg/kg diluted in a 10-cc syringe administered as an intravenous infusion over 10 minutes before induction of general anesthesia.

Category

Prevention

2**Description**

Control group: Participants in this group will receive 10 cc of normal saline administered as an intravenous infusion over 10 minutes before induction of general anesthesia.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ali ibn Abitaleb hospital and Khatam Al-Anbia hospital

Full name of responsible person

Asadullah Shakeri

Street address

Persian Gulf Highway, opposite Imam Khomeini Mosque, Ali ibn Abi Taleb hospital.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Saeideh Sarhaddi

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Persian Gulf Boulevard, Dr. Hesabi Square, University of Medical Sciences Campus, Building No. 1, Second Floor

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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

Zahedan 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**

Zahedan University of Medical Sciences

Full name of responsible person

Sareh Raeisi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

A Level or less

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