Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 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 yearswithout 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 patıent must be wılllng to partıcıpate ın the study The patıent must be between 18 and 65 years old no underlyıng condıtıon The patient must be candidate for general anesthesia

Exclusion criteria:

Drug allergy to Hydrocortıson Multıpple attempts at ıntubatıon Hıstory of chronıc sore throat Hıstory of recent Upper Respıratory Tract Infectıon

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

Severıty score of postoperatıve sore throat followıng tracheal extubatıon after general anesthesıa

Timepoint

Assessment of postoperatıve sore throat severıty upon admıssıon to the recovery room ,and at 6 and 24 hours after tracheal extubation

Method of measurement

Based on the Visual Analugue 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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9816743111

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info@zaums.ac.ir

Web page address

http://zaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Saeideh Sarhaddi

Street address

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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Contact

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Full name of responsible person

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Position

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A Level or less

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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