# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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.

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

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9816743111

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+98 54 3329 5570

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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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Persian Gulf Boulevard, Dr. Hesabi Square, University of Medical Sciences Campus,

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Email**
sare4884@gmail.com

## 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