Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the Effect of Intravenous Methylprednisolone Injection on Sore Throat Caused by General Anesthesia

Protocol summary

Study aim

General Objective:To evaluate the effect of intravenous administration of methylprednisolone on postoperative sore throat following general anesthesia in Ali Ibn Abi Talib and Khatam al-Anbia Hospitals, Zahedan.

Design

This Phase III randomized, triple-blind, parallel clinical trial will be conducted. 100 patients undergoing general anesthesia will be randomly assigned (1:1) to intervention and control groups using the RAND function in Excel.

Settings and conduct

This triple-blind randomized clinical trial aims to reduce postoperative sore throat after general anesthesia at Ali Ibn Abi Talib and Khatam al-Anbia Hospitals, Zahedan.Patients will be randomly assigned (1:1) by block randomization to either the methylprednisolone or placebo group.Allocation concealment will be ensured using sealed opaque envelopes.

Participants/Inclusion and exclusion criteria

Patients aged 18–65 who give informed consent and have no underlying disease, immunodeficiency, or methylprednisolone allergy will be included.Those with chronic sore throat, recent upper respiratory infection, or osteoporosis will be excluded.Uncooperative patients or those requiring multiple intubation attempts will also be withdrawn.

Intervention groups

In the intervention group, prior to induction of anesthesia, patients will receive Methylprednisolone succinate (manufactured by Jaber Ibn Hayyan Pharmaceutical Company) at a dose of 3 mg/kg, infused intravenously over 10 minutes using a 10-mL syringe.

Main outcome variables

Reduction of inflammation and pain, quality of postoperative care and patient satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251007067539N1**
Registration date: **2025-10-12, 1404/07/20**
Registration timing: **prospective**

Last update: **2025-10-12, 1404/07/20**
Update count: **0**

Registration date

2025-10-12, 1404/07/20

Registrant information

Name

Sadaf Jalili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 992 841 5720

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sadafjalili111@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-23, 1404/08/01

Expected recruitment end date

2026-03-17, 1404/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Intravenous Methylprednisolone Injection on Sore Throat Caused by General Anesthesia

Public title
Evaluation of the Effect of Intravenous Methylprednisolone Injection on Sore Throat Caused by General Anesthesia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The patient provides informed consent to participate in the study The patient's age is between 18 and 65 years. The patient has no known hypersensitivity to methylprednisolone. The patient has no underlying medical conditions The patient does not have any immunodeficiency disorders.

Exclusion criteria:
Known drug hypersensitivity to methylprednisolone. Lack of patient cooperation during the study. History of chronic sore throat. Recent history of upper respiratory tract infection. History of osteoporosis. Multiple attempts at tracheal intubation.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data and Safety Monitoring Board

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned to either the intervention or control group using a block randomization method with an equal allocation ratio (1:1). The randomization sequence will be generated by computer software and kept confidential. To ensure allocation concealment, the sequences will be placed in opaque, sealed, and sequentially numbered envelopes. Each patient who meets the inclusion criteria will select one envelope in order of enrollment and, based on its contents, will be assigned to either the intervention group (receiving intravenous methylprednisolone) or the control group (receiving placebo)

Blinding (investigator's opinion)
Triple blinded

Blinding description
Patients will be randomly assigned to either the intervention or control group using a block randomization method with an equal allocation ratio (1:1). The randomization sequence will be generated by computer software and kept confidential. To ensure allocation concealment, the sequences will be placed in opaque, sealed, and sequentially numbered envelopes. Each patient who meets the inclusion criteria will select one envelope in order of enrollment and, based on its contents, will be assigned to either the intervention group (receiving intravenous methylprednisolone) or the control group (receiving placebo)

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Zahedan University of Medical Sciences

Street address
Zahedan University of Medical Sciences, Dr. Hasabi Square

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Approval date
2025-10-05, 1404/07/13

Ethics committee reference number
IR.ZAUMS.REC.1404.222

Health conditions studied

1

Description of health condition studied
Sore throat from general anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain score

Timepoint
The Visual Analogue Scale(VAS) pain score will be recorded in both groups upon admission to the recovery room, 6 hours after extubation, and 24 hours after extubation.

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, prior to induction of anesthesia, patients will receive Methylprednisolone succinate (manufactured by Jaber Ibn Hayyan Pharmaceutical Company) at a dose of 3 mg/kg, infused intravenously over 10 minutes using a 10-mL syringe.
Category
Treatment - Drugs

2

Description
Control group: In the control group, 10 mL of normal saline will be infused intravenously over 10 minutes prior to induction of anesthesia.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali ebn Abitaleb hospital
Full name of responsible person
Dr.Kaveh Ouraei Yazdani
Street address
Ali ebn Abitaleb, in front of Imam Khomeini Mosque, Persian Gulf Highway
City
Zahedan
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Phone
+98 54 3329 5570
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hospital.aliebneabitaleb@gmail.com

2

Recruitment center
Name of recruitment center
Khatam al-Anbia Hospital
Full name of responsible person
Dr.Amir Gorgij
Street address
At the beginning of Jam Jam Boulevard, Khatam al-Anbia (PBUH) Square
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Zahedan
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9815733345
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Email
khatamhospital_zah@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Dr.Hassan Okati Aliabadi
Street address
Zahedan University of Medical Sciences, Dr. Hasabi Square, Zahedan
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Postal code
9816743463
Phone
+98 54 3337 2151
Email
zaums.research@zaums.ac.ir
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
1
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
Sadaf jalili
Position
Intern
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Person responsible for updating data

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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