

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of three different doses of intranasal dexamethasone in preventing sore throat after surgery in patients under general anesthesia

Protocol summary

Study aim

1. Determining and comparing the frequency distribution of sore throat in recovery (hours 2, 6, 12 and 24 hours) in the four studied groups 2. Determining and comparing the severity of sore throats in recovery (hours 2, 6, 12 and 24) in the four studied groups 3. Determining and comparing the first time to tolerate liquids and solids in the four studied groups 4. Determining the average time of the first request for additional pain relief in the four studied groups 5. Determining and comparing the average dose of additional painkillers in the four studied groups

Design

Clinical trial on four parallel groups, three-way blind, randomized, phase two on 100 patients

Settings and conduct

The use of dexamethasone and saline with a specific dose in four groups and a comparison of its effect on reducing sore throat after surgery under general anesthesia at Faiz Ophthalmology Center in Isfahan, where the patient, the clinical caregiver, and the outcome assessor are unaware of which drug was used for each patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. ASA-II 2. Age between 15-65 3. Candidate for surgery requiring tracheal tube 4. Completion of informed consent to participate in the study Exclusion criteria: 1. Presence of mental disorders 2. Active upper respiratory tract infection 3. History of chronic use of sedatives, alcohol and narcotics 4. Narcotics use 5. Allergy to the drugs used in the study 6. Severe obstructive pulmonary disease and asthma 7. History of recent corticosteroid therapy 8 Smokers 9. Pregnant women 10. People with nasal problems such as nasal polyps and nasal deviation

Intervention groups

Recipient of Dexamethasone (D1 , D2 , D3) and Saline

(S)

Main outcome variables

Severity of sore throat, cough, hoarseness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039326N23**

Registration date: **2023-07-27, 1402/05/05**

Registration timing: **prospective**

Last update: **2023-07-27, 1402/05/05**

Update count: **0**

Registration date

2023-07-27, 1402/05/05

Registrant information

Name

Hamidreza Shetabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2020

Email address

hamidshetabi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-05, 1402/05/14

Expected recruitment end date

2024-05-20, 1403/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of three different doses of intranasal dexamethasone in preventing sore throat after surgery in patients under general anesthesia

Public title

The effect of three different doses of intranasal dexamethasone in preventing sore throat after surgery in patients under general anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

ASAI-II Age between 18-65 Candidates for general surgery under anesthesia Completion of informed consent to participate in the study

Exclusion criteria:**Age**

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

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients are randomly divided into four groups using the table of random numbers resulting from the Random Allocation software.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, the patient, the clinical caregiver who records the data, and the data analyzer are unaware of the grouping of the patients and the studied drugs.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1**

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib BLVD

City

Esfahan

Province

Isfahan

Postal code**Approval date**

2023-07-16, 1402/04/25

Ethics committee reference number

IR.MUI.MED.REC.1402.155

Health conditions studied**1****Description of health condition studied**

sore throat

ICD-10 code

T88.8

ICD-10 code description

Other specified complications of surgical and medical care, not elsewhere classified

Primary outcomes**1****Description**

Sore throat

Timepoint

In recovery (every half hour) and in the ward (at zero hours, 2, 6, 12, and 24)

Method of measurement

Scoring system for sore throat,cough and hoarseness

2**Description**

Hoarseness

Timepoint

In recovery (every half hour) and in the ward (at zero hours, 2, 6, 12, and 24)

Method of measurement

Scoring system for sore throat,cough and hoarseness

3**Description**

Cough

Timepoint

In recovery (every half hour) and in the ward (at zero hours, 2, 6, 12, and 24)

Method of measurement

Scoring system for sore throat,cough and hoarseness

4

Description

Score of pain
Timepoint
In recovery (every half hour) and in the ward (at zero hours, 2, 6, 12, and 24)
Method of measurement
Visual Analogue Scale

5

Description
Total dose of analgesic
Timepoint
In the first 24 hours after the operation
Method of measurement
It is recorded in the data collection form

6

Description
Extubation time
Timepoint
After Extubation
Method of measurement
Clock

7

Description
Length of stay in recovery
Timepoint
After exiting recovery
Method of measurement
Clock

8

Description
Patient satisfaction score
Timepoint
At the end of 24 hours
Method of measurement
Likert scale

9

Description
Beginning time of using liquid foods
Timepoint
After using liquid foods
Method of measurement
Clock

10

Description
Beginning time of using solid foods
Timepoint
After using solid foods
Method of measurement
Clock

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After receiving 5 ml / kg of ringer lactate and pre-oxygenation for patients, the same anesthetic induction was performed including Fentanyl 2mcg / kg, Thiopental sodium 5 mg / kg and Atracurium 0.6mg / kg, and the patients underwent mechanical ventilation by mask for three minutes.Immediately before intubation,in group D1, dexamethasone 6 mg, in group D2, dexamethasone 8 mg, in group D3, dexamethasone 10 mg was administered intranasally.
Category
Prevention

2

Description
Control group: After receiving 5 ml / kg of ringer lactate and pre-oxygenation for patients, the same anesthetic induction was performed including Fentanyl 2mcg / kg, Thiopental sodium 5 mg / kg and Atracurium 0.6mg / kg, and the patients underwent mechanical ventilation by mask for three minutes.Immediately before intubation, 4 mg of normal salin was injected intra-nasal.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Feyz Hospital
Full name of responsible person
Hamidreza Shetabi
Street address
Modares st.
City
Esfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3445 2034
Email
hamidshetabi@med.mui.ac.ir

2

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Hamidreza Shetabi

Street address

Al-Zahra Therapeutic Training Center, Sofeh
Boulevard

City

Esfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 1818

Email

hamidshetabi@med.mui.ac.ir

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Feyz Hospital ,modares st

City

Esfahan

Province

Isfahan

Postal code

73461-81764

Phone

+98 31 3445 2034

Email

hamidshetabi@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Asgari

Street address

No 4, Medical university of Isfahan, Hezarjarib Ave.

City

Esfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 8138

Email

research@mui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

hamidreza shetabi

Position

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Hamidreza Shetabi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Feiz hospital, modarres St

City

Esfahan

Province

Isfahan

Postal code

73461-81764

Phone

+98 31 3668 8138

Email

hamidshetabi@med.mui.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Hamidreza Shetabi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Faiz Hospital, Modares St

City

Esfahan

Province

Isfahan

Postal code

73461-81764

Phone

+98 31 3445 2034

Email

hamidshetabi@med.mui.ac.ir

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