Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 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. ASAI-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

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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
Isfehan
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.

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2

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Hamidreza Shetabi

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Al-Zahra Therapeutic Training Center, Sofeh Boulevard
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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.
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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
Associate Professor
Latest degree
Specialist
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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