

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The prophylactic effect of intranasal dexamethasone on the postoperative sore throat

Protocol summary

Study aim

Determination of the Preventive Effect of Intranasal Dexamethasone on Sore throat after Surgery in General Anesthetized Patients

Design

Clinical trials in two community-based and pragmatic groups with parallel blinded, randomized, 40-person groups

Settings and conduct

Using Dexamethasone and Saline with a specific dose in two groups and comparing its effect on reducing sore throat after general anesthesia surgery in Fayyaz center of Isfahan, the patient and researcher are unaware of which drug is used for each patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged 18 to 65 years old, both of sex, candidates for eye surgery under general anesthesia, functional classes 1 and 2 of the American Society of Anesthesiologists (ASA), written informed consent to participate in the study. Exclusion criteria: Mental disorders, upper respiratory tract infection, History of chronic consumption of sedative, alcohol and narcotic drugs, allergies to the drugs used in the study, severe obstructive pulmonary disease and asthma, history of recent corticosteroid therapy. In the event of any complications during anesthetic induction, more than 1 time attempts to tracheal intubation, prolonged intubation time and using the laryngeal mask.

Intervention groups

Recipient of Dexamethasone (D) and Saline (S)

Main outcome variables

Severity of sore throat, cough, hoarseness.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039326N7**

Registration date: **2019-05-31, 1398/03/10**

Registration timing: **prospective**

Last update: **2019-05-31, 1398/03/10**

Update count: **0**

Registration date

2019-05-31, 1398/03/10

Registrant information

Name

Hamidreza Shetabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3620 2020

Email address

hamidshetabi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-08, 1398/03/18

Expected recruitment end date

2019-12-09, 1398/09/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The prophylactic effect of intranasal dexamethasone on the postoperative sore throat

Public title

Effect of intranasal dexamethasone on prevention of postoperative sore throat

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

candidate for eye surgery Age between 18-75 desire to participate in study American Society of Anesthesiologists(ASA) Physical Status Classification 1 or 2

Exclusion criteria:

mental disorders Active upper respiratory tract infection Alcohol or opioid addiction Allergies to used drugs History of Recent Corticosteroid Therapy History of chronic use of sedative medicines Severe obstructive pulmonary disease and asthma The occurrence of any anesthetic induction supply More than once trying to intubate Prolonged intubation time Use laryngeal mask

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation to intervention and control groups using a random number table

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind clinical trial after induction of anesthesia and 30 seconds before the tracheal intubation In the intervention group, dexamethasone (2 ml) and in the control group normal saline (2 ml) will be prescribed via the nostril.

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

۷۳۴۶۱-۸۱۷۴۶

Approval date

2019-03-19, 1397/12/28

Ethics committee reference number

IR.MUI.MED.REC.1397.374

Health conditions studied

1

Description of health condition studied

sore throat

ICD-10 code

Other spec

ICD-10 code description

T88.8

Primary outcomes

1

Description

sore throat

Timepoint

hours 0,2,4and6 after intubation

Method of measurement

scoring system for sore throat,cough and hoarseness

2

Description

hoarseness

Timepoint

hours 0,2,4and6 after intubation

Method of measurement

scoring system for sore throat,cough and hoarseness

3

Description

cough

Timepoint

hours 0,2,4and6 after intubation

Method of measurement

scoring system for sore throat,cough and hoarseness

4

Description

oxygen saturation percentage

Timepoint

hours 0,2,4and6 after intubation

Method of measurement

Pulse oximetry

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, 4 mg of dexamethasone was injected intra-nasal

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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81746-73461

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

shaqayeq haghjooye javamard

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vice chacellor of research and technology of
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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

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

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Position

Assistant 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