

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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)

###### Phone

+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

##### City

isfahan

##### Province

Isfahan

##### Postal code

81746-73461

##### 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

shaqayeq haghjooye javamard

#### Street address

vice chacellor of research and technology of university isfahan university of medical sciences hezarjerib st

#### City

isfahan

#### Province

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#### Postal code

81746-73461

#### Phone

+98 31 3668 0048

#### Email

sh\_haghjoo@med.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

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

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Feyz Hospital ,modares st

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## Person responsible for scientific inquiries

### Contact

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Esfahan University of Medical Sciences

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**Position**

Assistant professor

**Latest degree**

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## Person responsible for updating data

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**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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**Postal code**

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**Phone**

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**Email**

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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