

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison of the effect of nasal dexamethasone on post strabismus surgery nausea and vomiting prevention in adults

Protocol summary

Study aim

Comparison of the effect of nasal dexamethasone on post strabismus surgery nausea and vomiting prevention in adults

Design

Clinical trials in two community-based and pragmatic groups with parallel blinded, randomized, 30-person groups

Settings and conduct

Using intranasal Dexamethasone and Saline with a specific dose in two groups and comparing its effect on reducing nausea and vomiting after strabismus surgery in Feyz ophthalmology center of Isfahan, the patient and researcher are unaware of which drug is used for each patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: American Society of Anesthesiologists (ASA) Physical Status Classification 1 or 2; Age between 18 to 65 years; Candidate for strabismus surgery; filled informed consent form. Exclusion criteria: patients with motion sickness; taking anti emetic drugs during last 24 hours before surgery; patient under treatment with opioid drugs; smokers; pregnant women.

Intervention groups

Recipient of Dexamethasone (D) and Saline (S)

Main outcome variables

Severity of nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039326N12**

Registration date: **2020-03-19, 1398/12/29**

Registration timing: **prospective**

Last update: **2020-03-19, 1398/12/29**

Update count: **0**

Registration date

2020-03-19, 1398/12/29

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

2020-04-04, 1399/01/16

Expected recruitment end date

2020-09-06, 1399/06/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of nasal dexamethasone on post strabismus surgery nausea and vomiting prevention in adults

Public title

the effect of nasal dexamethasone on post strabismus surgery nausea and vomiting prevention

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

American Society of Anesthesiologists (ASA) Physical Status Classification 1 or 2 Age between 18 to 65 years Candidate for strabismus surgery filled informed consent form

Exclusion criteria:

patients with motion sickness taking anti emetic drugs during last 24 hours before surgery patient under treatment with opioid drugs smokers pregnant women

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation to intervention and control groups using Random allocation software

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind clinical trial, the patient and the observer who records data are unaware of patients groups and drugs which are being studied.

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

2020-02-01, 1398/11/12

Ethics committee reference number

IR.MUI.MED.REC.1398.563

Health conditions studied

1

Description of health condition studied

post operative nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

Incidence of nausea

Timepoint

2 and 24 hours after entering recovery

Method of measurement

Visual Analogue Scale

2

Description

Score of nausea

Timepoint

2 and 24 hours after entering recovery

Method of measurement

Visual Analogue Scale

3

Description

Incidence of vomiting

Timepoint

2 and 24 hours after entering recovery

Method of measurement

scoring system for vomiting

4

Description

Score of vomiting

Timepoint

2 and 24 hours after entering recovery

Method of measurement

scoring system for vomiting

5

Description

Incidence of pain

Timepoint

2 and 24 hours after entering recovery

Method of measurement

Visual Analogue Scale

6

Description

Score of pain

Timepoint

2 and 24 hours after entering recovery

Method of measurement

Visual Analogue Scale

7

Description

First time using anti emetic drug

Timepoint

24 hours after entering recovery

Method of measurement

Clock

8

Description

Total dose of anti emetic

Timepoint

24 hours after entering recovery

Method of measurement

file

9

Description

Total dose of analgesic

Timepoint

24 hours after entering recovery

Method of measurement

file

10

Description

Frequency of using anti emetic drug

Timepoint

24 hours after entering recovery

Method of measurement

file

11

Description

Extubation time

Timepoint

After Extubation

Method of measurement

Clock

12

Description

Length of stay in recovery

Timepoint

After exiting recovery

Method of measurement

Clock

13

Description

Patient satisfaction score

Timepoint

24 hours after entering recovery

Method of measurement

Likert scale

14

Description

Beginning time of using liquid foods

Timepoint

after using liquid foods

Method of measurement

Clock

15

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, Propofol 2 mg / kg and Atracurium 0.6mg / kg, and the patients underwent mechanical ventilation by mask for three minutes. Immediately before intubation, 1 cc of dexamethasone was injected in each nostril.

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, Propofol 2 mg / kg and Atracurium 0.6mg / kg, and the patients underwent mechanical ventilation by mask for three minutes. Immediately before intubation, 1 cc of normal saline was injected in each nostril.

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

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Isfahan

Postal code

81746-73461

Phone

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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 chancellor of research and technology of university isfahan, University of medical sciences, Hezarjerib st.

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vcr-office@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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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Assistant Professor

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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