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)
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+98 31 3620 2020
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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 datas 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

Isfehan

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.
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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 university isfahan, University of medical sciences, Hezarjerib st.
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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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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