Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial forcomparing of Ondansetrone, Metoclopramide And Midazolam for PONV prophylaxis in patients undergoing Strabismus surgery

Protocol summary

Summary

The aim of this study is to compare the efficacy of Ondansetron, Midazolam and Metoclopramide with placebo in preventing PONV following strabismus surgery. Inclusion Criteria : All candidates of strabismus surgery under general anesthesia with ASA class I-II. Exclusion criteria :any hypersensitivity to Ondansetrone; Metoclopramide Or Midazolam; any event causing change in anesthesia technique or ICU admission or death of the patient. One hundred and sixty patients will be allocated with simple randomization in 4 groups of 40 : " ON" group will receive Ondansetrone 0.05 mg/kg, Group "MT" will receive Metoclopramide 0.15 mg/kg, Group "MD" will receive Midazolam 0.03 mg/kg intravenously and "CT" group will receive the solution of NaCl 0.9% as placebo infused with the same volume and the same manner 30 minutes before the end of surgery. The study will be designed as blinded in a way that the physician who evaluate the data will be different from the one who prescribes the premeditation. The patients will be evaluated for nausea, vomiting, need and dosage of anti-emetic drugs, time of liquid and solid diet tolerance, drug complications and satisfaction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011920588N5**
Registration date: **2017-06-30, 1396/04/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-30, 1396/04/09

Registrant information

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Darioush Moradi Farsani
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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2017-01-21, 1395/11/02

Expected recruitment end date

2017-03-22, 1396/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial forcomparing of Ondansetrone, Metoclopramide And Midazolam for PONV prophylaxis in patients undergoing Strabismus surgery

Public title

Nausea and vomiting afterstabismus surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : All candidates of strabismus surgery under general anesthesia with American Society Of

Anesthesiologists (ASA) class I-II. Exclusion Criteria : Documented psychiatric disorders; any hypersensitivity to Ondansetrone, Metoclopramide or Midazolam; history of opium, alcohol, cigarette or benzodiazepines addiction؛ BMI over 25; pregnancy; chronic cough; history of malignant hyperthermia; history of using of any anti emetic drug 24 hours before surgery;Any event causing change in anesthesia technique or ICU admission or death of the patient.

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan University Of Medical Sciences

Street address
Islamic Republic Of Iran

City
Isfahan

Postal code
8174675731

Approval date
2016-03-12, 1394/12/22

Ethics committee reference number
ir.mui.rec.1394.3.1053

Health conditions studied

1

Description of health condition studied
Nausea and vomiting

ICD-10 code
k20-k31(k3

ICD-10 code description
Diseases of oesophagus, stomach and duodenum

Primary outcomes

1

Description
Vomiting

Timepoint
In recovery, first and second 6 hours and 12 hour s later

Method of measurement
Frequency

2

Description
Nausea

Timepoint
iIn Recovery, First And Second 6 Hours And 12 Hours Later

Method of measurement
VAS (visual analogous score)

Secondary outcomes

1

Description
First time of solid and liquid diet toleranse

Timepoint
During the first 24 hours after anesthesia

Method of measurement
Hour

2

Description
Total dose of antiemetic drug used

Timepoint
During The First 24 Hours After Anesthesia

Method of measurement
Milligram

3

Description
Drug complications

Timepoint
During The First 24 Hours After Anesthesia

Method of measurement
Frequency

Intervention groups

1

Description
Intervention Group : " ON" group will receive Ondansetrone 0.05 mg/kg.

Category
Prevention

2

Description
Placebo Group : "CT" group will receive the solution of NACL 0.9% as Placebo.
Category
Treatment - Drugs

3

Description
Intervention group : " MT" group will receive Metoclopramide 0.15 mg/kg intravenously.
Category
Treatment - Drugs

4

Description
Intervention group :" MD" group will receive Midazolam 0.03 mg/kg Intravenously.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Feiz University Hospital
Full name of responsible person
Darioush Morad iFarsani-asistent professor of anesthesia and critical care
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Department of anesthesia and critical care, Alzahra university hospital, Sofeh Bulvar, Isfahan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Isfahan University Of Medical Sciense
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty