

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Effect of Ondansetron, Metoclopramide and Dexamethasone on Post Operative Nausea Vomiting after strabismus surgery

Protocol summary

Summary

Post Operative Nausea Vomiting is a common complication after surgery that it is unpleasant and leads to delay in discharge and other complications. The incidence of Post Operative Nausea Vomiting after strabismus surgery is high so we must to prevent it. Medical and non- medical approaches use for this reason that Ondansetron, metoclopramide, dexamethasone are these drugs used for this. We dedicated to compare three drugs for the prevention after this surgery (for the differences between adverse effects and the selection of the best efficient drug) for this reasons in a double blind randomized clinical trial, 111 patients from 2 to 15 years old that scheduled for strabismus surgery were selected (after explaining the process of the trial, written informed consent obtained from participants). Then they were divided into three groups randomly, for the first group Ondansetron 0.1 mg/kg, second metoclopramide 0.15 mg/kg, third dexamethasone 0.15 mg/kg were administered and the incidence of Post Operative Nausea Vomiting and treatment of it notated in the first hour, 1 to 6, 6 to 12, 12 to 24 hours after surgery and then were analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012051138N4**

Registration date: **2011-01-05, 1389/10/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-01-05, 1389/10/15

Registrant information

Name

Fataneh Bakhshi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences, Vice Chancellor for Research

Expected recruitment start date

2007-11-04, 1386/08/13

Expected recruitment end date

2009-06-01, 1388/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Ondansetron, Metoclopramide and Dexamethasone on Post Operative Nausea Vomiting after strabismus surgery

Public title

Effect of Ondansetron, Metoclopramide and Dexamethasone on Post Operative Nausea Vomiting after strabismus surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1- The patients candidates for strabismus surgery between 2-15 years 2- physical class

status(ASA) I-II Exclusion criteria: 1-History of GI problems
2-History of known drug sensitivity to drugs used in study.

Age

From **2 years** old to **15 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **111**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Guilan University of Medical Sciences

Street address

siadati st.

City

Rasht

Postal code

Approval date

2007-12-22, 1386/10/01

Ethics committee reference number

442

Health conditions studied

1

Description of health condition studied

strabismus

ICD-10 code

H49-H50

ICD-10 code description

H50

Primary outcomes

1

Description

frequency of nausea and vomiting

Timepoint

In the first hour (recovery period) 1to 6 , 6 to 12 , 12to24 hours post - operation

Method of measurement

Questionnair

Secondary outcomes

1

Description

frequency of nausea and vomiting treatment

Timepoint

In the first hour (recovery period) 1to 6 , 6 to 12 , 12to24 hours post - operation

Method of measurement

questionnaire

Intervention groups

1

Description

Group A (ondansetron) 0.1mg/kg IV 30 minutes before ending surgery

Category

Treatment - Drugs

2

Description

Group B (metoclopramide) 0.15mg/kg IV 30 minutes before ending surgery

Category

Treatment - Drugs

3

Description

Group C (dexamethasone) 0.15mg/kg IV at the start of surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Dr Sudabeh Haddadi

Street address

Amiralmomenin Hospital

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences, Vice Chancellor for Research

Full name of responsible person

Susan Komaii

Street address

Siadati st.

City

Rasht

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Guilan University of Medical Sciences, Vice Chancellor for Research

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**

Guilan University of Medical Sciences

Full name of responsible person

Dr Sudabeh Haddadi

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Assistant professor

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Web page address

Person responsible for updating data

Contact

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