

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of Hemodynamic Changes in Administration of Ondansetron and Metoclopramide in Preventing Post Operative Nausea and Vomiting after Strabism Surgery

Protocol summary

Summary

This is a randomized double blind clinical trial performed on 96 patients with average age of 6-12y/o, ASA (American Society of Anesthesiologists) physical status I and II candidates for strabism surgery with general anesthesia between the years 2009 till July 2010. After obtaining approval of ethic committee of university, the study was conducted in Nikookari hospital, Tabriz University of Medical Sciences. Our exclusion criteria were as follows: The patients who received antiemetics during previous 24 hours, the patients suffering from liver, renal, gastrointestinal disorders and motion sickness. The patients were consecutively randomized into two groups, ondansetron (n=48) and group of metoclopramide (n=48). In this study ondansetron 50mg/kg and metoclopramide 150mg/kg administered intravenously five minutes before induction of general anesthesia after routine monitoring. By using Aldrete scoring system, the patients discharged from recovery room, of course documenting of postoperative nausea and vomiting by specific scoring systems were done with the help of one of the investigators not aware of the drug used in the operating room. After 0-2, 2-6 and 6-24 hours, patients and their family were incorporated for reporting of postoperative nausea and vomiting in the surgical ward.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101052496N5**

Registration date: **2011-02-19, 1389/11/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-02-19, 1389/11/30

Registrant information

Name

Hassan Soleimanpour

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1329 1286

Email address

soleimanpourh@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Vice chancellor of Tabriz University of Medical Sciences

Expected recruitment start date

2009-03-21, 1388/01/01

Expected recruitment end date

2010-05-22, 1389/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Hemodynamic Changes in Administration of Ondansetron and Metoclopramide in Preventing Post Operative Nausea and Vomiting after Strabism Surgery

Public title

Comparison of Hemodynamic Changes in Administration of Ondansetron and Metoclopramide in Preventing Post

Operative Nausea and Vomiting after Strabism Surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with average age of 6-12y/o, ASA (American Society of Anesthesiologists) physical status I and II candidated for strabism surgery with general anesthesia Exclusion criteria: The patients who received antiemetics during previous 24 hours, the patients suffering from liver, renal, gastrointestinal disorders and motion sickness

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **96**

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

Ethic committee of tabriz university of medical sciences

Street address

Ethic committee of university, Research Vice chancellor of Tabriz University of Medical Sciences , Tabriz University of Medical Sciences, Daneshgah Street, Tabriz-51664, I.R IRAN.

City

Tabriz

Postal code

51664

Approval date

2008-07-24, 1387/05/03

Ethics committee reference number

8733

Health conditions studied

1

Description of health condition studied

Strabism

ICD-10 code

H50.9

ICD-10 code description

Strabism, unspecified

Primary outcomes

1

Description

nausea

Timepoint

After 0, 2, 6 and 24 hours of surgery

Method of measurement

Zero for not having nausea - 1, for mild nausea- 2, for moderate nausea and 3 for sever nausea

Secondary outcomes

1

Description

vomiting

Timepoint

After 0, 2, 6 and 24 hours of surgery

Method of measurement

Zero for the patients not experiencing vomiting, 1 for the little vomiting, 2 for vomiting gastric contents and 3 for vomiting food particles.

Intervention groups

1

Description

Metoclopramide (Dopamine receptor antagonist used for the treatment of nausea and vomiting) 150mg/kg administered intravenously(at one time) five minutes before induction of general anesthesia after routine monitoring.

Category

Prevention

2

Description

Ondansetron (5HT3 antagonist anti-emetic used for the treatment of nausea and vomiting) 50mg/kg administered intravenously(at one time) five minutes before induction of general anesthesia after routine monitoring.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Nikookari ophthalmologic hospital

Full name of responsible person

Dr.Mohammadreza Afhami

Street address

Department of anesthesia, Tabriz University of medical Sciences, Tabriz, East Azarbaijan, Iran.

City

Tabriz

Postal code**Phone**

+98 41 1336 7494

Fax**Email**

Parvar.88@Gmail.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Research Vice chancellor of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mir Ali Eteraf Oskouei

Street address

Research Vice chancellor of Tabriz University of Medical Sciences, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz, East Azarbaijan, IRAN

City

Tabriz

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

Yes

Title of funding source

Research Vice chancellor of Tabriz University of Medical Sciences

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**

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Parvar Hassanzadeh Salmasi

Position

Assistant professor of Anesthesiology

Other areas of specialty/work**Street address**

Department of anesthesia, Tabriz University of medical Sciences, Tabriz, East Azarbaijan, Iran.

City

Tabriz

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Mohammadreza Afhami

Position

Associate Professor of Anesthesiology

Other areas of specialty/work**Street address**

Department of anesthesia, Tabriz University of medical Sciences, Tabriz, East Azarbaijan, Iran.

City

Tabriz

Postal code**Phone**

+98 41 1336 7494

Fax**Email**

afhami.reza@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Hassan Soleimanpour

Position

Anesthesiologist/Assistant professor of Anesthesiology, MD

Other areas of specialty/work**Street address**

Emergency Medicine Department, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz, I.R IRAN.

City

Tabriz

Postal code

51664

Phone

+98 41 1335 2078

Fax**Email**

h_mofid1357@yahoo.com

Web page address**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