

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Clinical trial for comparing of Ondansetron, 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 Ondansetron; 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 Ondansetron 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

##### Name

Darioush Moradi Farsani

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3625 5555

##### Email address

dmoradi@med.mui.ac.ir

#### 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 for comparing of Ondansetron, Metoclopramide And Midazolam for PONV prophylaxis in patients undergoing Strabismus surgery

#### Public title

Nausea and vomiting after strabismus 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 Ondansetron, 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 hours later

#### Method of measurement

Frequency

### 2

#### Description

Nausea

#### Timepoint

In 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 tolerance

#### 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 Ondansetron 0.05 mg/kg.

#### Category

Prevention

## 2

### Description

Placebo Group : "CT" group will receive the solution of NAACL 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

##### Street address

Department of anesthesia and critical care, Alzahra university hospital, Sofeh Bulvar, Isfahan, Iran

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Isfahan University Of Medical Science

##### Full name of responsible person

Dr Mehdi Nematbakhsh, Deputy Center Chaiman

##### Street address

Deputy center, Isfahan university of medical sciences, Sofeh Bulvar, Isfahan, Iran

##### City

Isfahan

##### 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 Science

##### 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

Isfahan University Of Medical Sciences

#### Full name of responsible person

Darioush Moradi Farsani

#### Position

Asistant professor of Anesthesia and Critical care

#### Other areas of specialty/work

#### Street address

Department of Anesthesia and Critical care, Alzahra university hospital, Sofeh Bulvar, Isfahan, Iran

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Isfahan University Of Medical Sciences

#### Full name of responsible person

Darioush Moradi Farsani

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Asistant professor of Anesthesia and Critical care

#### Other areas of specialty/work

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Isfahan university of medical sciences

**Full name of responsible person**

Darioush Moradi Farsani

**Position**

Asistant Professor of anesthesia and critical care

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

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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*