

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Comparing the effect of midazolam ,ondansetron and their combination on post strabismus surgery nausea-vomiting prevention

#### Protocol summary

##### Study aim

Determining the effect of midazolam,ondansetron and their combination on post strabismus surgery nausea-vomiting prevention

##### Design

This study will be conducted as a randomized double-blinded clinical trial in four groups. Randomization will be done by random allocation software .The number of patients in each group is 40 and the total sample size is 120. clinical trial will be conducted at phase 3.

##### Settings and conduct

This randomized double-blinded clinical trial will be conducted with 160 patients in Feyz hospital, Isfahan, Iran. In this study patients and researchers will be blinded.

##### Participants/Inclusion and exclusion criteria

1) ASA I-II 2) Age between 18-62 years 3) Candidate for strabismus surgery 4) The desire to participate in the study

##### Intervention groups

In this study patients are randomly divided into 4 groups: group m receive midazolam group o receive ondansetron group mo receive midazolam and ondansetron group s or control group receive normal saline

##### Main outcome variables

1) Nausea frequency 2) Nausea Intensity 3) Vomiting frequency 4) Vomiting intensity 5) Pain frequency 6) Pain intensity 7) Time of extubation 8) Recovery time 9) Patient satisfaction 10) Time of eating and drinking

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180416039326N8**

Registration date: **2019-08-08, 1398/05/17**

Registration timing: **prospective**

Last update: **2019-08-08, 1398/05/17**

Update count: **0**

##### Registration date

2019-08-08, 1398/05/17

##### Registrant information

###### Name

Hamidreza Shetabi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3620 2020

###### Email address

hamidshetabi@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-23, 1398/06/01

##### Expected recruitment end date

2020-03-20, 1399/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of midazolam ,ondansetron and their combination on post strabismus surgery nausea-vomiting prevention

##### Public title

Effect of midazolam ,ondansetron and their combination on post strabismus surgery nausea-vomiting

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

ASA I-II Candidate for strabismus surgery Age between 18-62 years The desire to participate in the study

**Exclusion criteria:**

Patient with motion sickness disease Receiving an anti-emetic drug in the last 24 hours Patient being treated with opioid Pregnant women smokers

**Age**

From **18 years** old to **62 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **160**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be done by Random allocation software.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This is a double blinded study. patients and researchers are unaware of patients groups and type of medication. The medications will be prepared by an anesthetist who is unaware of the patients groups and will be covered by an aluminium foil and encoded by an anesthetist. Demographic information, post surgical nausea and vomiting, patient satisfaction and other variable will be collected by a person who is not aware of the drugs and patients.

**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**

Isfahan university of medical sciences, Hezarjarib Ave, Isfahan, Iran

**City**

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**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2019-07-01, 1398/04/10

**Ethics committee reference number**

IR.MUI.MED.REC.1398.174

**Health conditions studied****1****Description of health condition studied**

Strabismus

**ICD-10 code**

H50.9

**ICD-10 code description**

Unspecified strabismus

**Primary outcomes****1****Description**

Intensity and frequency of nausea and vomiting

**Timepoint**

0-2 and 2-24 hours after surgery

**Method of measurement**

Calculating nausea-vomiting frequency by questionnaire and nausea-vomiting intensity by Visual Analogue Scale

**Secondary outcomes****1****Description**

pain frequency

**Timepoint**

1)First 0-2 hours 2) first 2-24 hours

**Method of measurement**

questionnaire

**2****Description**

Pain intensity

**Timepoint**

1)first 0-2 hours 2)first 2-24 hours

**Method of measurement**

Visual analogue scale

**3****Description**

Time of extubation

**Timepoint**

After the end of the surgery

**Method of measurement**

A Period between end of the surgery and extubation measured By anesthesiologist

## 4

### **Description**

Recovery time

### **Timepoint**

After the end of the surgery

### **Method of measurement**

A period between the end of the surgery and going to the ward that is measured by modified aldrete score

## 5

### **Description**

Patient satisfaction

### **Timepoint**

At the time of the patient discharge

### **Method of measurement**

Likert scale

## 6

### **Description**

Time of eating and drinking

### **Timepoint**

After the end of the surgery

### **Method of measurement**

The first time of eating and drinking After the surgery

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: The patients in the group one receive 0.75mg/kg intravenous midazolam after the beginning of the anesthesia .

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group 2: Patients in group 2 receive 4mg intravenous ondansetron after the beginning of the anesthesia.

#### **Category**

Treatment - Drugs

### 3

#### **Description**

Intervention group 3: Patients in group 3 receive combination of 0.75mg/kg midazolam and 4mg ondansetron intravenously after the beginning of the anesthesia.

#### **Category**

Treatment - Drugs

### 4

#### **Description**

Control group: Patient in this group receive 2cc normal saline intravenously after the beginning of the

anesthesia.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Feyz Hospital

##### **Full name of responsible person**

Hamidreza Shetabi

##### **Street address**

Feyz Hospital , Modares St

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

81746-73461

##### **Phone**

+98 31 3668 0048

##### **Email**

Hamidshetabi@med.mui.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Shaqayeq Haghjooye Javanmard

##### **Street address**

Vice chancellery of research and technology , Isfahan University of Medical Sciences, Hezarjarib St.

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##### **Email**

Sh\_haghjoo@med.mui.ac.ir

#### **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

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**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

**Street address**

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**Other areas of specialty/work**

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**Person responsible for scientific inquiries**

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**Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Postal code**

۷۳۴۶۱-۸۱۷۶۴

**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