

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The Comparison Effect Of ondansetron and Ginger on Incidence and Severity of Postoperative Nausea and Vomiting in Patients Undertaken Ophthalmic Surgery

#### Protocol summary

##### Summary

The aim of the study is to determine the effect of ondansetron and ginger on occurrence and severity of nausea and vomiting after eye surgery on patients. Participants in this study are 150 patients undergoing eye surgery. All patients were chosen to be between 18 and 60 years old, able to swallow capsules used in the study and also not sensitive to ginger or ondansetron. Sampling was done continuously based on availability. Participants were divided into three blocks. The first three persons were randomly chosen using three cards (A, B, C). Patients were randomized into three groups (receiving ginger, ondansetron and placebo). The severity of nausea and vomiting in patients were determined by a researcher who was unaware of the patients' treatment regime, using standard tools and a checklist. This was done once the patient was recovered, 2, 4 and 6 hours after the surgery.. Probable events(abdominal pain, heartburn, shortness of breath, diarrhea and insomnia) were recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014060918020N1**

Registration date: **2014-07-02, 1393/04/11**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-07-02, 1393/04/11

##### Registrant information

##### Name

Shahnam Sadigh Maroufi

##### Name of organization / entity

Faculty of Allied Medicine (IUMS)

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8670 4732

##### Email address

sedighmaroufi.s@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research of Iran University of Medical Sciences

##### Expected recruitment start date

2014-06-22, 1393/04/01

##### Expected recruitment end date

2014-10-23, 1393/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Comparison Effect Of ondansetron and Ginger on Incidence and Severity of Postoperative Nausea and Vomiting in Patients Undertaken Ophthalmic Surgery

##### Public title

The Comparison Effect Of ondansetron and Ginger on Postoperative Nausea And Vomiting after Ophthalmic Surgery

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion Criteria: Lack of cancer; Age 18 to 60 years; Ability to swallow capsules used in the study; Platelet

count above 100 thousand; Not suffering from intestinal obstruction and hepatitis; Not pregnant; Absence epilepsy, diabetes and kidney disease; Lack of anti-emetic drugs; Lack of long-term treatment with corticosteroids; No history of allergy to ginger or ondansetron Exclusion Criteria: Severe nausea and vomiting after surgery and require to use antisemitic

#### Age

From **18 years** old to **60 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **150**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Triple blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

##### Street address

Iran University Campus, Hemmat freeway, next to Milad tower Tehran, Iran

##### City

Tehran

##### Postal code

#### Approval date

2014-06-17, 1393/03/27

#### Ethics committee reference number

101568

## Health conditions studied

### 1

#### Description of health condition studied

Glaucoma

#### ICD-10 code

H40

#### ICD-10 code description

Glaucoma

### 2

#### Description of health condition studied

Paralytic strabismus

#### ICD-10 code

H49

#### ICD-10 code description

Paralytic strabismus

### 3

#### Description of health condition studied

cataract

#### ICD-10 code

H25

#### ICD-10 code description

capsular glaucoma with pseudoexfoliation of lens

## Primary outcomes

### 1

#### Description

Nausea

#### Timepoint

2,4,6 hours after surgery

#### Method of measurement

Using a Check lists and standard tools

### 2

#### Description

Vomiting

#### Timepoint

2,4,6 hours after surgery

#### Method of measurement

Using a Check lists and standard tools

## Secondary outcomes

### 1

#### Description

Cramp

#### Timepoint

2, 4, 6 hours after surgery

#### Method of measurement

Visual analysis and Scoring

### 2

#### Description

Heartburn

#### Timepoint

2, 4, 6 hours after surgery

#### Method of measurement

Visual analysis and Scoring

### **3**

**Description**

Dyspnea

**Timepoint**

2, 4, 6 hours after surgery

**Method of measurement**

Visual analysis and Scoring

### **4**

**Description**

diarrhea

**Timepoint**

2, 4, 6 hours after surgery

**Method of measurement**

Visual analysis and Scoring

### **5**

**Description**

Insomnia

**Timepoint**

2, 4, 6 hours after surgery

**Method of measurement**

Visual analysis and Scoring

## **Intervention groups**

### **1**

**Description**

Intervention 1: administration of ginger capsules contain 1000 mg drug with 30 cc water 1 hour before surgery

**Category**

Treatment - Drugs

### **2**

**Description**

Control: administration of placebo capsule with 30 cc water 1 hour before surgery

**Category**

Treatment - Drugs

### **3**

**Description**

Intervention 2: administration of Ondansetron capsules contain 16 mg drug with 30 cc water 1 hour before surgery

**Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

**Recruitment center****Name of recruitment center**

Rasool Akram Hospital

**Full name of responsible person**

Fereshte Kabiri

**Street address**

Satarkhan St.

**City**

Tehran

## **Sponsors / Funding sources**

### **1**

**Sponsor****Name of organization / entity**

Vice chancellor for research of Iran University of Medical Sciences

**Full name of responsible person**

Seyyed Ali Javad Mousavi

**Street address**

Iran University Campus, Hemmat FreeWay, Next to Milad Tower Tehran, Iran

**City**

Tehran

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

Yes

**Title of funding source**

Vice chancellor for research of Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Parisa Moradi Majd

**Position**

Master of Sciences

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

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## Person responsible for scientific inquiries

### Contact

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Shahnam Sadigh Maruofi

**Position**

PhD Student Of Medical Education

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## Person responsible for updating data

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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*