

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Comparing therapeutic impacts of Magnesium sulphate and ondansetron on propofol 2% injection pain in general anesthesia in patients undergoing vitrectomy operation

#### Protocol summary

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##### Summary

Present randomized clinical trial will perform for comparing analgesic impacts of magnesium sulfate and Ondansetron on propofol injection pain in patients undergoing vitrectomy operation. In this trial, 90 patients undergone general anesthesia within vitrectomy operation between September 2012 and April 2013 will include. Subjects randomly will allocate into three groups with 30 patients: (1) magnesium sulfate group (2) Ondansetron group and (3) Normal saline group as placebo group. Pain intensity of subjects will assess by a four-point scale in four time intervals (5, 10, 20 and 25 seconds) after injection.

##### Recruitment status

**Recruitment complete**

##### Funding source

Iran University of Medical Sciences

##### Expected recruitment start date

2012-08-01, 1391/05/11

##### Expected recruitment end date

2013-04-01, 1392/01/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013092613182N3**

Registration date: **2013-11-10, 1392/08/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-11-10, 1392/08/19

##### Registrant information

###### Name

Amir Bahrami-Ahmadi

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 912 496 9707

###### Email address

##### Scientific title

Comparing therapeutic impacts of Magnesium sulphate and ondansetron on propofol 2% injection pain in general anesthesia in patients undergoing vitrectomy operation

##### Public title

Assessment of Magnesium sulphate and ondansetron on propofol 2% injection pain

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion: patients undergoing vitrectomy operation using general anesthesia with American Society of Anesthesiologists physical status I and II. Exclusion: known sensitivity to propofol or ondansetron; receiving analgesic or sedative medication in the last 24 hours; presence of infection on the dorsum of the left hand; indications for rapid sequence intubation; presence of cardiac conduction defects; epilepsy; and use of antiarrhythmic medications, thin dorsal veins, renal and liver diseases, neuro-muscular diseases, pregnant

women, and uncooperative patients were excluded

### Age

From **20 years** old to **70 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **90**

### 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

Ethical Committee of Iran university of medical sciences

##### Street address

Theran-Iran

##### City

Research ethical committee, research deputy, Iran university of Medical Sciences, Hemat highway, Teh

##### Postal code

##### Approval date

2012-08-19, 1391/05/29

##### Ethics committee reference number

21781

## Health conditions studied

### 1

#### Description of health condition studied

Propofol injection pain

#### ICD-10 code

Y48.2

#### ICD-10 code description

Other and unspecified general anaesthetics

## Primary outcomes

### 1

#### Description

Propofol injection pain

#### Timepoint

5, 10, 20 and 25 seconds after trial intervention

#### Method of measurement

with 4 points scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

patients in ondansetron group: received four milligrams ondansetron

#### Category

Prevention

### 2

#### Description

Patients in magnesium sulfate group: received 150 mg magnesium sulfate

#### Category

Treatment - Drugs

### 3

#### Description

patients in placebo group: 3 milliliter normal saline 0.9%

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rasoul Akram Hospital

##### Full name of responsible person

Dr Hamid Reza Faiz

##### Street address

Niayesh street, Satarkhan street, Tehran, Iran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Dr Hamid Reza Faiz

##### Street address

Faculty of Medicine, Iran university of medical sciences, Hemmat highway, 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**

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**

Dr Amir Bahrami-Ahmadi

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Researcher

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**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*