

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

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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

Position

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