

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### The Effect of Magnesium Sulfate on Reducing Intraocular Pressure during Laparoscopic Cholecystectomy

#### Protocol summary

##### Summary

**Objectives:** The aim of this study was to investigate the prophylactic effect of magnesium sulfate on the intraocular pressure in patients undergoing laparoscopic cholecystectomy. This study is a randomized, double-blind clinical trial. Inclusion criteria: age of eighteen years and above, ASA I and II, weighting between 50 to 80 kg, patients who had been scheduled for laparoscopic cholecystectomy. Exclusion criteria: arrhythmia, heart diseases, musculoskeletal diseases like myasthenia Grove, kidney failure, acute or chronic eye disease, history of using any drugs that affects intraocular pressure. Patients were randomly divided into two groups of intervention group who received 30 mg/kg magnesium sulfate and patients in control group received 20 cc, normal saline. Sample Size: 40 patients found eligible based on the inclusion criteria.

**Interventions:** The magnesium sulfate was solved in 100cc normal saline and infused within 20 minutes in the treatment group, and 100 cc normal saline was infused to patients in control group before the operation. The possibility of Magnesium toxicity was quite low with this dose but neurological examinations were done for every patient. Mean arterial blood pressure, heart rate, intraocular pressure, (paw) peak and plate airway pressure, ETCO<sub>2</sub> were measured, continuously during the operation. Tetracaine eye drop was used before measuring intraocular pressure via Tonopen. CO<sub>2</sub> insufflation was done in supine position and peritoneal gas pressure was maintained at 12 mmHg during the operation. Primary and secondary outcome measures were to investigate the prophylactic effect of magnesium sulfate on the intraocular pressure during laryngoscopy, intubation and CO<sub>2</sub> insufflation.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014122219470N6**

Registration date: **2015-01-09, 1393/10/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-01-09, 1393/10/19

##### Registrant information

###### Name

Farzaneh Masihi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3647 4270

###### Email address

masihif@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research, Shiraz University of Medical Science

##### Expected recruitment start date

2014-02-01, 1392/11/12

##### Expected recruitment end date

2014-10-01, 1393/07/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Magnesium Sulfate on Reducing Intraocular Pressure during Laparoscopic Cholecystectomy

## Public title

Prophylactic Effect of Magnesium Sulfate on Intraocular Pressure Rising during Laparoscopic Cholecystectomy

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: Adult patients, ASA I and II, weighting between 50 to 80 kg, Patients who had been Scheduled for Laparoscopic Cholecystectomy. Exclusion criteria: Arrhythmia in ECG, Cardiac Disease, Musculoskeletal Diseases like Myasthenia Grove, Renal Failure, Acute or Chronic Eye Disease, History of Using any Drugs that Affects Intraocular Pressure.

## Age

From **18 years** old to **85 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **40**

## 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

Ethic Committee of Shiraz University Of Medical Sciences

##### Street address

Central Building of Shiraz University of Medical Sciences, Zand Street

##### City

Shiraz

##### Postal code

##### Approval date

2010-09-23, 1389/07/01

##### Ethics committee reference number

CP-P-9336-3696

## Health conditions studied

### 1

#### Description of health condition studied

Increased Intraocular Pressure

#### ICD-10 code

H40.0

#### ICD-10 code description

Ocular Hypertension

## Primary outcomes

### 1

#### Description

Effect of Magnesium Sulfate on the Intraocular Pressure

#### Timepoint

During Larangoscopy and Intubation

#### Method of measurement

Tonopen

## Secondary outcomes

### 1

#### Description

Effect of Magnesium Sulfate on the Intraocular Pressure

#### Timepoint

During CO2 Insufflation

#### Method of measurement

Tonopen

## Intervention groups

### 1

#### Description

Intervention Group: The Magnesium Sulfate was Solved in 100cc Normal Saline and Infused within 20 Minutes in the Treatment Group

#### Category

Treatment - Drugs

### 2

#### Description

Control group: 100 cc Normal Saline was Infused to Patients in the Control Group Before the Operation

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Namazee Hospital

##### Full name of responsible person

Abdolsamad Saleh

##### Street address

Anesthesiology Office, Namazi Hospital, Zand Street

##### City

## Sponsors / Funding sources

**1**

### Sponsor

**Name of organization / entity**

Vice Chancellor for Research, Shiraz University of Medical Sciences

**Full name of responsible person**

Dr Seyd Basir Hashemi

**Street address**

Vice Chancellor for Research, Shiraz University of Medical Sciences, 7th floor-Central Building of Shiraz University of Medical Sciences, Zand Street

**City**

Shiraz

**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, Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Abdolsamad Saleh

**Position**

Physician, Anesthesiology Resident

**Other areas of specialty/work**

**Street address**

Anesthesiology Department, Shahid Faghihi Hospital, Zand street

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saleha@sums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Dr Reza Joybar

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Anesthesiologist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Farzaneh Masihi

**Position**

English Consultant, Anesthesiology Research Center Staff

**Other areas of specialty/work**

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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*

