Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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, ETCO2 were measured, continuously during the operation. Tetracaine eye drop was used before measuring intraocular pressure via Tonopen. CO2 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 CO2 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)

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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

Shiraz

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

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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

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Person responsible for updating data

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English Consultant,Anesthesiology Research Center Staff

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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*