

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the effect of intravenous magnesium sulfate on hemodynamic changes induced by pneumoperitoneum in patients undergoing laparoscopic cholecystectomy in Firoozgar Hospital during 91-92 years

Protocol summary

Summary

The aim of this study is to evaluate the effect of intravenous magnesium sulfate on hemodynamic effects induced by blowing carbon dioxide in patients undergoing laparoscopic cholecystectomy. It is a randomized double-blind placebo-controlled clinical trial over population of patients who are candidates for laparoscopic gallbladder removal surgery. The main criterias for inclusion are, patients scheduled for laparoscopic cholecystectomy with pneumoperitoneum by CO₂, aged 70-20 years, ASA class I- II, and exclusion criteria: chronic use of beta-adrenergic blockers and calcium channel blockers, the willingness of to participate in the Plan and the occurrence of comoplications. The calculated sample size is 60 (2N), patients will go under similar anesthesia. Before induction of anesthesia, in magnesium group, 50 mg/ kg of magnesium sulfate in 100 cc of normal saline and in conyrol group only 100 cc normal saline over 10 minutes will be infused. Mean arterial blood pressure and heart rate, peripheral oxygen saturation, and end expiratory carbon dioxide levels in both groups before and after induction, before pneumoperitoneum, and then every 10 minutes until 60 minutes after pneumoperitoneum will be recorded by automatic Hemodynamic monitoring. After the operation, the pain and the hemodynamic variables, postoperative shivering, nausea and vomiting, the patient's comfort during recovery, would be evaluated. After collecting and recording data, SPSS program will use to analyze and evaluate the differences between the two groups of patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013022311398N2**

Registration date: **2013-04-06, 1392/01/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-04-06, 1392/01/17

Registrant information

Name

Mohammad Reza Ghodrati

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 6762

Email address

m-ghodrati@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Deputy of Medicine Faculty, Tehran University of Medical Sciences

Expected recruitment start date

2012-09-23, 1391/07/02

Expected recruitment end date

2013-06-21, 1392/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of intravenous magnesium sulfate on hemodynamic changes induced by pneumoperitoneum in patients undergoing laparoscopic cholecystectomy in Firoozgar Hospital during 91-92 years

Public title

The effect of magnesium sulfate on hemodynamic complications of laparoscopy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: consent to participate in research projects - patients scheduled for surgery of laparoscopic cholecystectomy with pneumoperitoneum gas CO₂ - Age 70-20 years - physical patients with class ASA I-II .
Exclusion criteria: chronic use of drugs beta-adrenergic and calcium-channel blockers - drugs, psychotropic substances, use of lithium, other drugs such as hemodynamic TCA - history of cardiovascular diseases - sensitivity to magnesium sulfate - diseases such as hypertension, diabetes mellitus, renal disease, acute cholecystitis and endocrine or metabolic disease. Cases who develop complications also would be excluded.
Also conversion of laparoscopic cholecystectomy to open surgery because of technical problems.

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Tehran University Of Medical Sciences Ethic Committee

Street address

Tehran University Of Medical Sciences, Ghods St.

Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2012-09-23, 1391/07/02

Ethics committee reference number

91/d/1361/130

Health conditions studied

1

Description of health condition studied

Laparoscopic cholecystectomy

ICD-10 code

K80.2

ICD-10 code description

Calculus of gallbladder without cholecystitis

Primary outcomes

1

Description

Mean arterial blood pressure

Timepoint

Before and after induction, before pneumoperitoneum, and every 10 minutes after pneumoperitoneum and after surgery

Method of measurement

Will be recorded by Automatic Hemodynamic Monitoring

2

Description

Heart Rate

Timepoint

Before and after induction, before pneumoperitoneum, and every 10 minutes until 60 minutes after pneumoperitoneum and after surgery

Method of measurement

Will be recorded by Automatic Hemodynamic Monitoring

Secondary outcomes

1

Description

Rate of usage of Propofol

Timepoint

One time at the end of surgery

Method of measurement

The mean dose per kilogram of body weight per minute

2

Description

Sedation quality of the patient in recovery

Timepoint

Every 15 minutes

Method of measurement

Clinical evaluation using Ramsay sedation score system

3

Description

Patient's pain acuity during recovery

Timepoint

Every 15 minutes

Method of measurement

According to VAS rating score

4

Description

TNG consumption rate

Timepoint

End of study

Method of measurement

Measuring amount of consumed drug

Intervention groups

1

Description

In the intervention group before induction of anesthesia, infusion of 50 mg/kg of body weight magnesium sulfate in 100 cc of normal saline over 10 minutes.

Category

Prevention

2

Description

In the placebo group and for blinding of patients and observers before induction of anesthesia 100 ml of normal saline will be infused intravenously in 10 min.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Firouzgar Hospital

Full name of responsible person

Mohammad Reza Ghodraty MD. Assistant Professor of Anesthesiology

Street address

Anesthesiology Department, Firouzgar Hospital, Beh-Afarin St. Karim Khan Av.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Medicine Faculty, Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhoundzadeh Basti MD.

Street address

Faculty of Medicine, Pour Sina Ave, Keshavarz Blvd.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Deputy of Medicine Faculty, Tehran 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

Tehran University of Medical Science

Full name of responsible person

Ali Mougouee MD.

Position

Anesthesia Resident

Other areas of specialty/work

Street address

Anesthesiology Department, Firouzgar Hospital, Beh-Afarin St. Karim Khan Av.

City

Tehran

Postal code

Phone

+98 21 8214 1360

Fax

Email

dr_mougouee@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Ghodraty MD.

Position

Assistant Professor of Anesthesiology

Other areas of specialty/work

Street address

Department of Anesthesiology, Firouzgar Hospital,
Beh-Afarin St. Karim Khan Av.

City

Tehran

Postal code**Phone**

+98 21 8894 6762

Fax**Email**

m-ghodrati@tums.ac.ir mrghodrati@yahoo.com

Web page address**City**

Tehran

Postal code**Phone**

+98 21 8894 6762

Fax**Email**

m-ghodrati@tums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Science

Full name of responsible person

Mohammad Reza Ghodrati MD.

Position

Assistant Professor of Anesthesiology

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

Anesthesiology Department, Firouzgar Hospital, Beh-
Afarin St. Karim Khan Av.

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