# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 Ghodraty

**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 develope 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 acuty 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 weigth magnesium sulfate in 100 cc of normal saline over 10 minutes.
**Category**
Prevention

**2**

**Description**
In the plasebo group and for blining 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**
Anesthesiolgy 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**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Tehran University of Medical Science
**Full name of responsible person**
Mohammad Reza Ghodraty MD.
**Position**
Assistant Professor of Anesthesiology
**Other areas of specialty/work**
**Street address**
Anesthesiology Department, Firouzgar Hospital, Beh-Afarin St. Karim Khan Av.
**City**
Tehran
**Postal code**
**Phone**
+98 21 8894 6762
**Fax**
**Email**
m-ghodrati@tums.ac.ir
**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*