

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Evaluation the effect of magnesium sulfate in comparison with lidocaine on hemodynamic changes after endotracheal intubation and carbon dioxide insufflation in patients who undergo laparoscopic cholecystectomy: a clinical trial

#### Protocol summary

##### Summary

Goals: Evaluation the effect of magnesium sulfate in comparison with lidocaine on hemodynamic changes after endotracheal intubation and carbon dioxide insufflation in patients who undergo laparoscopic cholecystectomy. Current study is a randomized, triple-blind clinical trial conducted on 60 patients (30 cases and 30 controls) undergoing laparoscopic cholecystectomy referring to Imam Khomeini Hospital in both genders (age range: 18-70 years). Patients, individuals who were responsible for assessing variables and analyzing data were unaware of how patients have been put in groups. Patients were divided into two experimental and control groups, randomly. First, two boxes with A and B codes were provided, then medications were given to anesthesia technician and he/she was asked to put medications into one of the boxes. Then, researcher selected randomly one of the boxes and the injection was performed. Current study is in phase 2 of clinical trial. Patients with allergy to magnesium sulfate: hypermagnesemia: hypertension: morbid obesity: and severe hepatic, renal, endocrine and cardiac dysfunction were excluded from the study. Studied medications included magnesium sulfate 30 mg/kg, and lidocaine 1.5 mg/kg which were diluted to 20 ml by adding distilled water. In patients with severe hemodynamic changes, the following therapeutic interventions were performed: for bradycardia (heart rate less than 60 per minute), intravenous bolus dose of 0.6 mg injection atropine, for hypotension (mean arterial pressure less than 60 mmHg), increasing the rate of intravenous fluid injection and/or intravenous bolus dose of injection phenylephrine. Mean arterial pressure and heart rate were recorded as follows: (1) basic vital signs, (2) before laryngoscopy, (3) after endotracheal intubation (in 1-5 minute intervals), (4) before carbon

dioxide insufflation, (5) 5 minutes after carbon dioxide insufflation, (6) 15 minutes after carbon dioxide insufflation, and (7) 30 minutes after carbon dioxide insufflation.

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2016022716612N6**  
Registration date: **2016-09-09, 1395/06/19**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-09-09, 1395/06/19

##### Registrant information

###### Name

Khatereh Isazadehfar

###### Name of organization / entity

Ardabil University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 45 1225 1693

###### Email address

kh.isazadehfar@arums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ardabil University Of Medical Sciences

##### Expected recruitment start date

2016-03-19, 1394/12/29  
**Expected recruitment end date**  
2016-07-22, 1395/05/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Evaluation the effect of magnesium sulfate in comparison with lidocaine on hemodynamic changes after endotracheal intubation and carbon dioxide insufflation in patients who undergo laparoscopic cholecystectomy: a clinical trial

**Public title**  
The effect of magnesium sulfate on hemodynamic changes in patients undergoing laparoscopic cholecystectomy

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
Inclusion criteria: Patients of both genders who referred to Imam Khomeini Hospital Of Ardabil for laparoscopic cholecystectomy (age range: 18-70 years). Exclusion criteria: Allergy to magnesium sulfate! hypermagnesemia! hypertension! morbid obesity! and severe hepatic, renal, endocrine, and cardiac dysfunction

**Age**  
From **18 years** old to **70 years** old

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
Closed boxes randomization method was used in current study

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee Of Ardabil University Of Medical Sciences

**Street address**

Daneshgah St, Ardabil

**City**

Ardabil

**Postal code**

**Approval date**

2015-10-04, 1394/07/12

**Ethics committee reference number**

IR.ARUMS.REC.1394.44

**Health conditions studied**

1

**Description of health condition studied**

Laparoscopic cholecystectomy

**ICD-10 code**

k80, k81,

**ICD-10 code description**

Cholelithiasis, Cholecystitis, Other diseases of gallbladder

**Primary outcomes**

1

**Description**

Blood pressure changes

**Timepoint**

Basic vital signs, before laryngoscopy, after endotracheal intubation (in 1-5 minute intervals), before carbon dioxide insufflation, 5 minutes after carbon dioxide insufflation, 15 minutes after carbon dioxide insufflation, 30 minutes after carbon dioxide insufflation

**Method of measurement**

In mmHg, with barometer

2

**Description**

Heart rate changes

**Timepoint**

Basic vital signs, before laryngoscopy, after endotracheal intubation (in 1-5 minute intervals), before carbon dioxide insufflation, 5 minutes after carbon dioxide insufflation, 15 minutes after carbon dioxide insufflation, 30 minutes after carbon dioxide insufflation

**Method of measurement**

Counting heart beats

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group: Magnesium sulfate 30 mg/kg which was diluted to 20 ml by adding distilled water. Medications were injected immediately after venipuncture.

### Category

Treatment - Drugs

## 2

### Description

Control group: Intravenous lidocaine 1.5 mg/kg which was diluted to 20 ml by adding distilled water. Medications were injected immediately after venipuncture.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital

##### Full name of responsible person

Dr. Masood Entezari

##### Street address

Ardabil

##### City

Ardabil

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Ardabil University Of Medical Sciences

##### Full name of responsible person

Dr. Akbar Pirzadeh

##### Street address

Daneshgah St, Ardabil

##### City

Ardabil

##### 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, Ardabil 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

Ardabil University Of Medical Sciences

#### Full name of responsible person

Dr. Masood Entezari

#### Position

Anesthesiologist

#### Other areas of specialty/work

#### Street address

Daneshgah St, Ardabil

#### City

Ardabil

#### Postal code

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#### Phone

+98 45 3325 1688

#### Fax

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#### Email

M.entezari @arums.ac.ir

#### Web page address

-

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Ardabil University Of Medical Sciences

#### Full name of responsible person

Dr. masood entezari

#### Position

Anesthesiologist

#### Other areas of specialty/work

#### Street address

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Ardabil University Of Medical Sciences

#### Full name of responsible person

Dr. Masood Entezari

**Position**

Anesthesiologist

**Other areas of specialty/work**

**Street address**

Daneshgah St, Ardabil

**City**

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**Phone**

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**Fax**

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**Email**

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**Web page address**

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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*