Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 boxed 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
-
Phone
+98 45 3325 1688
Fax
-
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
Daneshgah St, Ardabil
City
Ardabil
Postal code
Phone
+98 45 3325 1688
Fax
Email
M.entezari@arums.ac.ir
Web page address

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
Ardabil
Postal code
-
Phone
-
Fax
-
Email
-
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