Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Study of the Effect of Intravenous Infusion of Magnesium Sulfate on the Level of Intraoperative End-Tidal CO2 and Postoperative Pain in Laparoscopic Cholecystectomy

Protocol summary

Study aim

A Study of the Effect of Intravenous Infusion of Magnesium Sulfate on the Level of Intraoperative End-Tidal CO2 and Postoperative Pain in Laparoscopic Cholecystectomy

Design

This study is a Randomized Clinical Trial Study that will be performed in Rafsanjan. The study sample consisted of 62 patients with laparoscopic cholecystectomy. Patients are divided into two groups of 31 intervention and control using a random number table. The magnesium group received 50 mg/kg of Mg sulfate IV in 100 cc normal saline 0.9% and the control group 100 cc N.S 0.9%. CO2 will be recorded by the anesthesia resident before and after surgery, and the severity of postoperative pain during recovery, the second, sixth, 12th, and 24th hours will be measured using the Visual Analogue Scale (VAS). Data on patients' personal information are collected and recorded using a checklist. Also, the amount of changes in end-expiratory carbon dioxide, used opium dose and VAS index in the mentioned hours will be compared between the two groups and will be statistically analyzed by SPSS 21 software.

Settings and conduct

In this double-blind study, 62 patients of laparoscopic cholecystectomy will be presented in Ali Ibn Abitaleb Hospital of Rafsanjan.

Participants/Inclusion and exclusion criteria

62 patients with laparoscopic cholecystectomy with inclusion criteria including ASA classification I-II patients, 20 to 60 years of age and exclusion criteria including: drug hypersensitivity to magnesium sulfate, drug abuse, any neuromuscular disease, EF less than 40% and hypotension or bradycardia during anesthesia by more than 20%, cardiac disease, hepatic failure and kidney failure, chronic respiratory failure and morbid obesity.

Intervention groups

Mg group receives 50 mg/kg of Mg sulfate IV in 100 cc of N.S 0.9% and control group 100 cc of N.S 0.9%.

Main outcome variables

End-Tidal CO2 Pain Severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210302050549N1**
Registration date: **2021-03-27, 1400/01/07**
Registration timing: **prospective**

Last update: **2021-03-27, 1400/01/07**
Update count: **0**

Registration date

2021-03-27, 1400/01/07

Registrant information

Name

Mahbube Akhundi Saleh Abad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 8590

Email address

mahbubeakhundi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-10-07, 1400/07/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A Study of the Effect of Intravenous Infusion of Magnesium Sulfate on the Level of Intraoperative End-Tidal CO2 and Postoperative Pain in Laparoscopic Cholecystectomy

Public title
A Study of The Effect of Magnesium Sulfate on End-Tidal CO2 and Pain
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
ASA I-II patients 20 to 60 years of age
Exclusion criteria:
Drug allergy to magnesium sulfate Drug abuse Any neuromuscular disease (Ejection Fraction)EF < 40% Hypotension or Bradycardia by more than 20% during anesthesia Cardiac disease Hepatic or Renal failure Chronic respiratory failure Morbid obesity
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
This study is performed by simple randomization method using Random Number Table tool and the randomization unit is individual. Random Number Table is a set of numbers that is generated without a specific pattern or order and in a completely random form and has become a table. To use the table of random numbers, the researcher first determines the table to read the numbers from top to bottom. The second assumption of the researcher is to consider numbers for different groups, in which even numbers are considered for the case group and odd numbers for the control group. The researcher then touches one of the numbers and moves in one of the predetermined directions and records the numbers and assigns them to two groups (case and control). Random allocation concealment method in this study is SNOSE method. In this method, first a random sequence is performed, then based on the size of the research sample, a number of envelopes with aluminum wrappers are prepared and each of the random sequences created is registered on a card and the cards are placed inside the envelope. In order to maintain a random sequence, envelopes are numbered in the same way on the outer surface of the envelopes. Finally, the lids of the envelopes are glued and placed in a box, respectively. At the beginning of the registration of participants, one of the envelopes of the letter is opened and the assigned group of the participant is revealed according to the order of entry of the eligible participants. In the implementation phase of the random allocation process of this study, cases such as the individual who created the random sequence, the person who examined the participants in terms of inclusion and exit criteria, and the participants who studied and participated in the study. Assigned, it is intended that on this basis, three separate individuals perform the randomization process without being aware of the actions of other researchers.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, each participant is assigned a code that the data analyzer and the participant are unaware of which group the assigned code belongs to.
Placebo
Used
Assignment
Parallel
Other design features
Participants in this study are divided into two groups of intervention (case) and control

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Ethics Committee of Rafsanjan University of Medical Sciences
Street address
Ali-ebn-Abitaleb Hospital, Imam Ali Blvd
City
Rafsanjan
Province
Kerman
Postal code
7717933777
Approval date
2021-01-18, 1399/10/29
Ethics committee reference number
IR.RUMS.REC.1399.235

Health conditions studied

1

Description of health condition studied
End-Tidal CO2

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
End-Tidal CO2
Timepoint
During surgery
Method of measurement
With capnograph device

2

Description
Pain severity
Timepoint
After surgery during recovery, second, sixth, 12th and 24th hours
Method of measurement
Using the VAS (Visual Analogue Scale)

Secondary outcomes

1

Description
Blood Pressure
Timepoint
During Surgery
Method of measurement
Blood Pressure Cuff

2

Description
Heart Rate
Timepoint
During Surgery
Method of measurement
ECG (electrocardiogram) Monitoring

Intervention groups

1

Description
The intervention group receives 50 mg/kg of magnesium sulfate IV in 100 cc of normal saline 0.9%
Category
Rehabilitation

2

Description
The control group receives 100cc of 0.9% normal saline
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali Ibn Abitaleb Hospital of Rafsanjan
Full name of responsible person
Mahbube Akhundi
Street address
Ali Ibn Abitaleb Hospital, Imam Ali Blvd
City
Rafsanjan
Province
Kerman
Postal code
7717933777
Phone
+98 34 3428 0000
Email
m.akhondi@rums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Ali Shamsizadeh
Street address
Rafsanjan University of Medical science, Imam Ali Blvd
City
Rafsanjan
Province
Kerman
Postal code
7717933777
Phone
+98 34 3428 0038
Email
alishamsy@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rafsanjan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Mahbube Akhundi Saleh Abad
Position
Anesthesiology Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
No. 41, 6/1 Ave, Aboozar St. Rafsanjan City
City
Rafsanjan
Province
Kerman
Postal code
7717745767
Phone
+98 34 3428 8590
Fax
Email
m.akhondi@rums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Mahbube Akhundi Saleh Abad
Position
Anesthesiology Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
No. 41, 6/1 Ave, Aboozar St. Rafsanjan City
City
Rafsanjan
Province
Kerman
Postal code
7717745767
Phone
+98 34 3428 8590
Fax
Email
m.akhondi@rums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Mahbube Akhundi Saleh Abad
Position
Anesthesiology Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
No. 41, 6/1 Ave, Aboozar St. Rafsanjan City
City
Rafsanjan
Province
Kerman
Postal code
7717745767
Phone
+98 34 3428 8590
Fax
Email
m.akhondi@rums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available