Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Comparison study of two doses of magnesium sulfate on hemodynamic response to endotracheal intubation in laparoscopic cholecystectomy

Protocol summary

Study aim
Comparison of the effects of magnesium sulfate at a dose of 30mg / kg compared to a dose of 40mg / kg on responses Hemodynamics of tracheal intubation in patients undergoing CABG

Design
A randomized, placebo-controlled, placebo-controlled clinical trial on patients undergoing CABG

Settings and conduct
Patients III-IIASA are candidates for CABG Elective Surgery at Kashan Shahid Beheshti Hospital with EF greater than 40%. After obtaining written consent, they will be randomly divided into 4 groups with 4 blocks each. The operation continues until morning. Age, sex, weight, height, chronic illness and medications are recorded. All patients receive 1mg and 0.1mg / kg intramuscular morphine as pre-medication the night before surgery and one hour before surgery. After entering the operating room, patients are monitored by pulse oximeter, electrocardiogram, and non-invasive blood pressure.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients III-ASA II elective CABG candidate with EF greater than 40%. And ages 18 to 75 years. Exclusion criteria: Emergency surgery - Probability of intubation problem - Magnesium sulfate sensitivity

Intervention groups
Group A: Magnesium sulfate is infused at 30mg / kg within 5 minutes, which continues before induction.
Group B: Magnesium sulfate 40mg / kg is infused over a period of 5 minutes, which continues before induction.
Group C: Normal saline equivalent to group

Main outcome variables
Body Mass Index, Systolic Pressure, Diastolic Pressure, Medium Blood Pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191229045935N1**
Registration date: **2020-03-04, 1398/12/14**
Registration timing: **retrospective**

Last update: **2020-03-04, 1398/12/14**
Update count: **0**

Registration date
2020-03-04, 1398/12/14

Registrant information

Name
Jafar Kazemeini

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 5550 0111

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kazemeini-j@mail.kaums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-27, 1397/12/08

Expected recruitment end date
2019-08-30, 1398/06/08

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison study of two doses of magnesium sulfate on hemodynamic response to endotracheal intubation in laparoscopic cholecystectomy

Public title
The effect of two different doses of the drug on hemodynamic responses in patients undergoing laparoscopic cholecystectomy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
ASA II-III Patients Candidate for Laparoscopic Elective Cholecystectomy
Exclusion criteria:
Emergency Surgery Probability of intubation problem Sensitivity to magnesium sulfate Cardiac arrhythmia Serum creatinine above 2 mg / dl pregnant women Patients with severe heart valve disorders Patients with aortic stenosis
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
0
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients III-IASA were candidates for elective laparoscopic elective cholecystectomy at Shahid Beheshti Hospital in Kashan after obtaining written consent random blocks with 6 blocks are divided into 3 groups. In the case of central hiding randomization, in this method, the random sequence is assigned to a particular person or center and sampling is performed at one or more centers simultaneously. Based on the order of the participants' entry into the study, the researcher communicates with the relevant center and asks about the random assignment of the participant to a specific group.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients from two different doses of magnesium sulfate are completely blind to their hemodynamic responses.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kashan university of medical sciences, Qotbe Ravandi Blvd, Kashan
Street address
Kashan university of medical sciences, Qotbe Ravandi Blvd, Kashan
City
Kashan
Province
Isfehan
Postal code
8711111111
Approval date
2019-02-12, 1397/11/23
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1397.106

Health conditions studied

1

Description of health condition studied
Patients undergoing CABG
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Heart rate
Timepoint
At the time of tracheal, and 2, 4, 6, and 10 minutes after tracheal intubation.
Method of measurement
Digital barometer

2

Description
systolic blood pressure, diastolic blood pressure, and mean blood pressure
Timepoint
systolic blood pressure, diastolic blood pressure, and mean blood pressure before infusion to induction were recorded at different time points, including anesthesia induction, at the time of tracheal, and 2, 4, 6, and 10 minutes after tracheal intubation.
Method of measurement
Mercury barometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Magnesium sulfate 30mg / kg infusion within 5 minutes which continues before induction. The studied drugs were manufactured by Judge Tabriz Company from Alborz Broadcasting Company and recorded at the time of tracheal intubation, 2, 4, 6 and 10 minutes after tracheal intubation.nd 10 minutes after tracheal intubation.

Category
Treatment - Drugs

2

Description
Intervention group: Magnesium sulfate 40mg / kg is infused for 5 minutes and continues until induction. The studied drugs were manufactured by Judge Tabriz Company from Alborz Broadcasting Company and recorded at the time of tracheal intubation, 2, 4, 6 and 10 minutes after tracheal intubation.

Category
Treatment - Drugs

3

Description
Control group: Normal saline equal to the intervention group as placebo, which is infused like the other two groups within 5 minutes and will continue until induction.The studied drugs were manufactured by Judge Tabriz Company from Alborz Broadcasting Company and recorded at the time of tracheal intubation, 2, 4, 6 and 10 minutes after tracheal intubation.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Kashan Shahid Beheshti Hospital

Full name of responsible person
Mohammadreza Tashakor

Street address
Kashan university of medical sciences, Qotbe Ravandi Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Kashan 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
Kashan University of Medical Sciences

Full name of responsible person
Jafar Kazemeini

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is 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

Title and more details about the data/document
Some portion of the dose information can be shared.

When the data will become available and for how long
Starting access after printing the article.

To whom data/document is available
All researchers

Under which criteria data/document could be used
For use in surgeries

From where data/document is obtainable
Author corresponding

What processes are involved for a request to access data/document
An in-person or written request by email

Comments