Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of dexmedetomidine and magnesium sulfate in controlling hemodynamic changes in patients undergoing laparoscopic cholecystectomy

Protocol summary

Study aim

The aim of this study was to evaluate the efficacy of dexmedetomidine and magnesium sulfate on hemodynamic responses during laparoscopic cholecystectomy.

Design

Randomized double-blind placebo-controlled clinical

Settings and conduct

Pneumoperitoneum as consequence of laparoscopic surgery would cause hemodynamic unstability. Effect of different medication on reduction unfavorable aspects of pneumoperitoneum is been reported. In this study, it was compared the efficacy of dexmedetomidine and magnesium sulfate on hemodynamic responses during laparoscopic cholecystectomy in Kashan Shahid Beheshti Hospital. The patients were divided into 3 groups in a random manner. In control group (C), normal saline was infused, Dexmedetomidine group (D) received 1µg/kg Dexmedetomidine and then 0.5µg/kg/hr and magnesium sulfate group (M) received 2 gr magnesium sulfate and then 0.9mg/kg/hr. Participants were unaware of which group they were in. The clinical caregiver recording the data was not aware of the type of patient group.

Participants/Inclusion and exclusion criteria

Population of study are sujects that candidate for laparoscopic gallbladder removal surgery. Inclusion criteria: patients Candidate for Laparoscopic Cholecystectomy Surgery in Kashan Shahid Beheshti Hospital, patients 18-65 years, Level one and two class A.S.A (American society of anesthesiologists), Blood pressure less than or equal to 140/190

Intervention groups

In Dexmedetomidine (D) group, dexmedetomidine solution in normal saline, in magnesium sulfate (S) group, magnesium sulfate solution in normal saline and normal saline were as a placebo injected in the control group (C).

Main outcome variables

Systolic blood pressure; Diastolic blood pressure; Mean arterial blood pressure; Heart Rate; o2 saturation, Intra-abdominal pressure; End-Tidal CO2; Bispectral index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191220045829N1**
Registration date: **2021-09-27, 1400/07/05**
Registration timing: **retrospective**

Last update: **2021-09-27, 1400/07/05**
Update count: **0**

Registration date

2021-09-27, 1400/07/05

Registrant information

Name
Reza ArefNezhad
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

2017-09-23, 1396/07/01

Actual recruitment end date

2019-03-11, 1397/12/20

Trial completion date

2019-12-05, 1398/09/14

Scientific title

Comparison of the effect of dexmedetomidine and magnesium sulfate in controlling hemodynamic changes in patients undergoing laparoscopic cholecystectomy

Public title

Comparison of the effect of dexmedetomidine and magnesium sulfate in patients undergoing laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients Candidate for Laparoscopic Cholecystectomy Surgery in Kashan Shahid Beheshti Hospital Patients 18-65 years Level one and two class A.S.A (American society of anesthesiologists) Blood pressure less than or equal to 140/190

Exclusion criteria:

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **75**

Actual sample size reached: **61**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization was used to randomly assign people to three groups and to ensure that the number of people in groups is balanced. Participants randomly had been divided into three groups: dexmedomidine, magnesium sulfate, and control. One envelope was opened for each patient, each envelope had a random number. It had been predetermined that each random number belongs to one of the three groups mentioned.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants consented to participate in the study but were unaware of which group they were in. The clinical caregiver recording the data was not aware of the type of patient group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

8715988141

Approval date

2016-11-16, 1395/08/26

Ethics committee reference number

IR.KAUMS.REC.1395.82

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

Systolic blood pressure

Timepoint

Before and after pre-drug injection, after induction, after intubation, after blowing gas, every 10 minutes up to 40 minutes and after extubation

Method of measurement

It was recorded by a monitor device attached to the patient.

2

Description

Diastolic blood pressure

Timepoint

Before and after pre-drug injection, after induction, after intubation, after blowing gas, every 10 minutes up to 40 minutes and after extubation

Method of measurement

It was recorded by a monitor device attached to the patient.

3

Description
Mean arterial blood pressure
Timepoint
Before and after pre-drug injection, after induction, after intubation, after blowing gas, every 10 minutes up to 40 minutes and after extubation
Method of measurement
It was recorded by a monitor device attached to the patient.

4

Description
Heart Rate
Timepoint
Before and after pre-drug injection, after induction, after intubation, after blowing gas, every 10 minutes up to 40 minutes and after extubation
Method of measurement
It was recorded by a monitor device attached to the patient.

5

Description
o2 saturation
Timepoint
Before and after pre-drug injection, after induction, after intubation, after blowing gas, every 10 minutes up to 40 minutes and after extubation
Method of measurement
Pulse oximtery

6

Description
Intra-abdominal pressure
Timepoint
every 10 minutes up to 40 minutes
Method of measurement
Manometer

7

Description
End-Tidal CO2
Timepoint
Before and after pre-drug injection, after induction, after intubation, after blowing gas, every 10 minutes up to 40 minutes and after extubation
Method of measurement
Capnograph device

8

Description
Bispectral index
Timepoint
Before and after pre-drug injection, after induction, after intubation, after blowing gas, every 10 minutes up to 40 minutes and after extubation
Method of measurement
It was recorded by a monitor device attached to the patient.

Secondary outcomes

1

Description
Recovery time
Timepoint
From the the rejection of patient's endotracheal intubation to the number 9 of the Aldrete criteria
Method of measurement
Aldrete criteria

2

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

Intervention groups

1

Description
Intervention group: Dexmedetomidine 1µg/kg was injected intravenously in 20 ml normal saline for ten minutes before induction of anesthesia, and dexmedetomidine 0.5µg/kg per hour after induction of it.
Category
Prevention

2

Description
Intervention group: Before induction of anesthesia, 4ml magnesium sulfate 50% (2gr) was infused in 20 ml normal saline for ten minutes and after induction of it, magnesium sulfate 50% (0.9mg/kg) was infused intravenously per hour.
Category
Prevention

3

Description
Control group: Normal saline was injected intravenously in 20 ml volume for ten minutes before and after induction of anesthesia.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center

Kashan shahid beheshti hospotal
Full name of responsible person
مهدی رجبی
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Person responsible for updating data

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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