Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison the effect of Dexmedetomidine and Magnesium Sulphate on hemodynamic changes during laparoscopic cholecystectomy surgery

Protocol summary

Summary

(1) Objective: Comparison the effect of Dexmedetomidine and Magnesium Sulphate on hemodynamic changes during laparoscopic cholecystectomy surgery (2) Design: Double blind randomized controlled trial (3) Setting and conduct: Selecting 90 patients undergoing cholecystectomy surgery in 5 Azar tertiary hospital affiliated to Golestan university of medical sciences and assigning them to three groups by simple random allocation method. (4) Participants including major eligibility criteria: age between 18 to 55 years; American Society of Anesthesiologists (ASA) physical status classification system I and II; under general anesthesia and tracheal intubation; filling the written informed consent form. Exclusion Criteria: with cardiovascular, hepatic, and renal diseases; substance abuse; Body Mass Index (BMI) greater than 30; Mallampati classification class III and IV. (5) Intervention: Intravenous infusion of Midazolam (1 mg/cc) and Fentanyl (100 mcg) as premedication 10 minute before anesthesia for three groups; isofolran-N2O and oxygenation with 100% FiO2 as anesthesia maintenance during surgery for 3 group. Then, intravenous infusion of Dexmedetomidine (0.5 mg/kg in 100 cc normal saline during 15 minute) for first group, Magnesium Sulphate (2 gr in 100 cc normal saline intravenous fluid during 15 minute) for second group; and Normal saline intravenous fluid (100 cc during 15 minute) for third group. Anesthesia with Sodium Thiopental (5 mg/ kg), and Atracurium (0.2 mg/ kg) and Fentanyl (1 mg/ kg) and tracheal intubation for 3 groups. Then, intravenous infusion of maintenance dosage of Dexmedetomidine (0.4 mg/kg/hr) for first group, Magnesium Sulphate (15 mg/ kg/ hr) for second group; and Normal saline intravenous fluid for third group. At the end of the surgery, discontinuation of intravenous infusions and isofolran-N2O and intravenous injection of Atropine (0.02 mg/kg) and Neostigmine (0.5 mg/ kg) and tracheal extubation and transferring patients with Modified Aldret Score ≥ 9 from recovery to surgery unit. (6) Main outcome measures (variable): Systolic and diastolic blood pressure; mean arterial pressure (MAP); Heart rate (HR); and shivering after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017092136312N1**
Registration date: **2017-10-05, 1396/07/13**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-10-05, 1396/07/13

Registrant information

Name

Sahar Kamyab

Name of organization / entity

Golestan university of Medical Sciences, Gorgan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 17 3235 4936

Email address

kamyab@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Golestan University of Medical Sciences, Gorgan, Iran

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-01-21, 1396/11/01

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

Scientific title
Comparison the effect of Dexmedetomidine and Magnesium Sulphate on hemodynamic changes during laparoscopic cholecystectomy surgery

Public title
Comparison the effect of Dexmedetomidine and Magnesium Sulphate on hemodynamic changes during laparoscopic cholecystectomy surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Participants including major eligibility criteria: age between 18 to 55 years old; American Society of Anesthesiologists (ASA) physical status classification system I and II; under general anesthesia and tracheal intubation; filling the written informed consent form. Exclusion Criteria: with cardiovascular, hepatic, and renal diseases; substance abuse; Body Mass Index (BMI) greater than 30; Mallampati classification class III and IV.
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Golestan University of Medical Sciences
Street address
Shastkola Road, Educational Campus of Golestan University of Medical Sciences, Gorgan, Iran
City
Gorgan
Postal code
4934174515
Approval date
2017-08-13, 1396/05/22
Ethics committee reference number
IR.GOUMS.REC.1396.128

Health conditions studied

1

Description of health condition studied
Cholecystectomy
ICD-10 code
Z90.4
ICD-10 code description
Acquired absence of other parts of digestive tract

Primary outcomes

1

Description
Systolic and diastolic blood pressure
Timepoint
Before, during, and after surgery
Method of measurement
By sphygmomanometer and in millimeter mercury

2

Description
Heart rate
Timepoint
Before, during, and after surgery
Method of measurement
withnon-invasive hemodynamic monitoring device and in beat per minute

3

Description
Mean Arterial Pressure (MAP)
Timepoint
Before, during, and after surgery
Method of measurement
derived from Systolic Blood Pressure and Diastolic Blood Pressure and in millimeter mercury

Secondary outcomes

1

Description
Shivering
Timepoint
after surgery
Method of measurement

observation of patient

Intervention groups

1

Description

First intervention group: Intravenous infusion of Midazolam (1 mg/cc) and Fentanyl (100 mcg) as premedication 10 minute before anesthesia; isofolran-N2O and oxygenation with 100% FiO2 as anesthesia maintenance during surgery.Then, intravenous infusion of Dexmedetomidine (0.5 mg/kg in 100 cc normal saline during 15 minute). Anesthesia with Sodium Thiopental (5 mg/ kg), and Atracurium (0.2 mg/ kg) and Fentanyl (1 mg/ kg) and tracheal intubation. Then, intravenous infusion of maintenance dosage of Dexmedetomidine (0.4 mg/kg/hr). At the end of the surgery, discontinuation of intravenous infusions and isofolran-N2O and intravenous injection of Atropine (0.02 mg/kg) and Neostigmine (0.5 mg/ kg) and tracheal extubation and transferring patients with Modified Aldret Score ≥ 9 from recovery to surgery unit.

Category

Treatment - Drugs

2

Description

Second intervention group: Intravenous infusion of Midazolam (1 mg/cc) and Fentanyl (100 mcg) as premedication 10 minute before anesthesia; isofolran-N2O and oxygenation with 100% FiO2 as anesthesia maintenance during surgery. Then, intravenous infusion of Magnesium Sulphate (2 gr in 100 cc normal saline intravenous fluid during 15 minute). Anesthesia with Sodium Thiopental (5 mg/ kg), and Atracurium (0.2 mg/ kg) and Fentanyl (1 mg/ kg) and tracheal intubation. Then, intravenous infusion of maintenance dosage of Magnesium Sulphate (15 mg/ kg/ hr). At the end of the surgery, discontinuation of intravenous infusions and isofolran-N2O and intravenous injection of Atropine (0.02 mg/kg) and Neostigmine (0.5 mg/ kg) and tracheal extubation and transferring patients with Modified Aldret Score ≥ 9 from recovery to surgery unit.

Category

Treatment - Drugs

3

Description

Placebo group: Intravenous infusion of Midazolam (1 mg/cc) and Fentanyl (100 mcg) as premedication 10 minute before anesthesia; isofolran-N2O and oxygenation with 100% FiO2 as anesthesia maintenance during surgery. Then, intravenous infusion Normal saline intravenous fluid (100 cc during 15 minute). Anesthesia with Sodium Thiopental (5 mg/ kg), and Atracurium (0.2 mg/ kg) and Fentanyl (1 mg/ kg) and tracheal intubation. Then, intravenous infusion of Normal saline intravenous fluid. At the end of the surgery, discontinuation of intravenous infusions and isofolran-N2O and intravenous injection of Atropine (0.02 mg/kg) and Neostigmine (0.5 mg/ kg) and tracheal extubation and transferring patients with Modified Aldret Score ≥ 9 from recovery to surgery unit.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

5 Azar tertiary hospital

Full name of responsible person

Dr. Sahar Kamyab

Street address

5th Azar street, 5 Azar tertiary hospital, Gorgan, Golestan province, Iran.

City

Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Golestan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hossein Taziki

Street address

Shastkola Road, Educational Campus of Golestan University of Medical Sciences, Gorgan, Iran

City

Gorgan

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, Golestan 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

Golestan University of Medical Sciences

Full name of responsible person
Dr. Sahar Kamyab
Position
Anesthesiology resident
Other areas of specialty/work
Street address
5th Azar street, 5 Azar tertiary hospital, Golestan province, Gorgan, Iran.
City
Gorgan
Postal code
Phone
+98 17 3235 4936
Fax
Email
Kamyab@goums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Golestan University of Medical Sciences
Full name of responsible person
Dr. Kazem Kazem Nejad
Position
Anesthesiologist
Other areas of specialty/work
Street address
5th Azar street, 5 Azar tertiary hospital, Gorgan, Golestan province, Iran
City
Gorgan
Postal code
Phone
+98 17 3235 4936
Fax
Email
Kamyab@goums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Golestan University of Medical Sciences
Full name of responsible person
Dr. Sahar Kamyab
Position
Anesthesiology resident
Other areas of specialty/work
Street address
5th Azar street, 5 Azar tertiary hospital, Gorgan, Golestan Province, Iran
City
Gorgan
Postal code
Phone
+98 17 3235 4936
Fax
Email
Kamyab@goums.ac.ir
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