

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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; isofluran-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 isofluran-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)

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+98 17 3235 4936

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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

with non-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**

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Full name of responsible person

Dr. Sahar Kamyab

Position

Anesthesiology resident

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

Dr. Kazem Kazem Nejad

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Other areas of specialty/work**Street address**

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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