Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Comparison Effects of Dexmedetomidine and Clonidine as Premedication in Perioperative Hemodynamic Stability and Post-op Pain in Laparoscopic Cholecystectomy

Protocol summary

Study aim
Comparison Effects of Dexmedetomidine and Clonidine as Premedication in Perioperative Hemodynamic Stability and Post-op Pain in Laparoscopic Cholecystectomy

Design
Double Blinded Randomized Clinical Trial

Settings and conduct
The study is performed in the operating room of Faghihi Hospital in Shiraz, after the anesthesiologist in charge of the study randomly divided patients into three groups. . Clonidine and placebo tablets are given by the ward nurse who is unaware of the study groups. Dexmetomidine and normal saline (placebo) infusions are also provided by an anesthesiologist who is unaware of the study groups. Drugs and placebo are then administered by the anesthesia personnel in the operating room. After transferring the patient to the recovery room, no information will be given to the recovery staff.

Participants/Inclusion and exclusion criteria
Inclusion Criteria:Patients Candidate for Laparoscopic Cholecystectomy Surgery Age 18-65 years Class (ASA) I, II. Exclusion Criteria:Communication problem Hypertension Heart disease Anemia Liver and Kidney Diseases Hormonal diseases Concurrent acute or chronic pain Gastrointestinal problems Sexual disorders CNS disorders Respiratory allergy Diabetes Pregnancy Duration of surgery more than 120 minutes.

Intervention groups
Intervention group 1:we start the dexmedetomidine infusion at a dose of 0.2 µg / kg). Patients are given a tablet similar to clonidine 30 minutes before induction. Intervention group 2:Oral administration of 0.2 mg clonidine 30 minutes prior to surgery and normal saline infusion begins with the same volume of dexmedomidine group (40 cc) as placebo.

Main outcome variables
Blood Pressure ,Nausea and Vomiting ,Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141009019470N96**
Registration date: **2020-01-20, 1398/10/30**
Registration timing: **prospective**

Last update: **2020-01-20, 1398/10/30**
Update count: **0**

Registration date
2020-01-20, 1398/10/30

Registrant information

Name
Farzaneh Masihi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3647 4270

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masihif@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-04, 1398/11/15

Expected recruitment end date
2020-06-04, 1399/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison Effects of Dexmedetomidine and Clonidine as Premedication in Perioperative Hemodynamic Stability and Post-op Pain in Laparoscopic Cholecystectomy

Public title
The effect of dexmedetomedine and clonidine on hemodynamics and postoperative pain of laparoscopic cholecystectomy

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients Candidate for Laparoscopic Cholecystectomy Surgery Age 18-65 years Class (ASA) I, II

Exclusion criteria:
Communication problem Hypertension Heart disease Anemia Liver and Kidney Diseases Hormonal diseases Concurrent acute or chronic pain Gastrointestinal problems Sexual disorders CNS disorders Respiratory allergy Diabetes Pregnancy Duration of surgery more than 120 minutes

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

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **135**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples were divided into 3 groups of 45 individuals using permutation block randomization method, obtained from WWW.Randomization.org.

Blinding (investigator's opinion)
Double blinded

Blinding description
The anesthesiologist in charge of carrying out the study based on a randomization chart divides the patients into three groups. Clonidine and placebo tablets are given to patients by a ward nurse who is unaware of the study groups. And the infusion of dexmedomidine and normal saline (placebo) is also provided by an anesthesiologist who is unaware of study groups and is provided by anesthesia staff in the operating room. After the patient is transferred to the recovery room, no information will be given to the recovery staff. And the patient, the anesthesia resident, the recovery nurse, and the inpatient and nurse analyzer are all blind to the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City
Shiraz

Province
Fars

Postal code
7134844119

Approval date
2019-12-16, 1398/09/25

Ethics committee reference number
IR.SUMS.MED.REC.1398.520

Health conditions studied

1

Description of health condition studied
Laparoscopic Cholecystectomy

ICD-10 code
K80.44

ICD-10 code description
Calculus of bile duct with chronic cholecystitis without obstruction

Primary outcomes

1

Description
Blood Pressure

Timepoint
Before induction, after induction, at the onset of surgery and every 5 minutes until the end of the surgery.

Method of measurement
Monitoring

2

Description
Pain

Timepoint
At the onset of recovery and thereafter every 15 minutes until recovery discharge .

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Nausea and Vomiting
Timepoint
At the onset of recovery and thereafter every 15 minutes until recovery discharge .
Method of measurement
Nausea and vomiting grading scale

2

Description
Sedation
Timepoint
At the onset of recovery and thereafter every 15 minutes until recovery discharge
Method of measurement
Ramsay sedation scale

Intervention groups

1

Description
Intervention group: Dexmedetomidine infusion (Hospira, INC, Lake Forest, IL 60045 USA) is initiated 5 min before surgical incision at a dose of 0.2 µg / kg.One dose of clonidine similar to placebo (placebo made by Shiraz University of Medical Sciences Pharmacy) was given to patients 30 minutes before induction.
Category
Prevention

2

Description
Intervention group:Oral administration of 0.2 mg clonidine (Razavi Pharmaceutical Service Institute) 30 minutes prior to surgery and normal saline infusion begins with the same volume of dexmedomidine group (40 cc) as placebo (placebo made by Shiraz University of Medical Sciences Pharmacy) .
Category
Prevention

3

Description
Control group:The control group received only oral placebo (placebo made by Shiraz University of Medical Sciences Pharmacy) and normal saline in the same volume as the dexmedomidine group (40 cc).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Faghihi Hospital
Full name of responsible person
Zahra Rafati
Street address
Shahid Faghihi Hospital, Zand Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Younes Ghasemi
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Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand street
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sacrc@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Zahra Rafati

Position
Anesthesiology Resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Anesthesiologist

Latest degree
Subspecialist

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Person responsible for updating data

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BS in anesthesia/English Consultant

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Master

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Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Its against our policies.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available