

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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. Dexmedetomidine 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 dexmedetomidine 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 dexmedetomidine 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 analyzer

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 dexmedetomidine 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 dexmedetomidine group (40 cc).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Faghihi Hospital

Full name of responsible person

Zahra Rafati

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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

Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

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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

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

Contact

Name of organization / entity

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Full name of responsible person

Mohammad Hosein Eghbal

Position

Anesthesiologist

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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BS in anesthesia/English Consultant

Latest degree

Master

Other areas of specialty/work

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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