Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of premedication with oral clonidine on hemodynamics and recovery status of patients undergoing laparoscopic cholecystectomy

Protocol summary

Study aim
Effect of premedication with oral clonidine on hemodynamics and recovery status of patients undergoing laparoscopic cholecystectomy.

Design
120 patients that meet the inclusion criteria after surgery finished and the patient is discharged from anesthesia will be selected as research sample and then divided into intervention and control groups with binary blocking.The intervention group will receive clonidine and the control group will receive placebo. The study is a randomized, double-blind,placebo-controlled clinical trial.

Settings and conduct
Patients in operation room of Imam Reza hospital will be randomly divided into two groups according to the random number table.The intervention group received 0.5 mg clonidine and the control group will receive the same amount of placebo half an hour before surgery. Given that the study is double-blind. Both clonidine and placebo medications will be prepared each morning by the number of surgeries and number required by the plan's administrator. Envelope A contains oral clonidine and envelope B is a placebo. Each patient will receive the envelopes based on whether they are A or B coded by an anesthetist who is blinded of the type of drug.In this study patient and anesthesiologist is blinded.

Participants/Inclusion and exclusion criteria
Entry requirements:All ASA I patients aged 20-65 years who are candidate for laparoscopic cholecystectomy. Exclusion criteria: Blood loss over 10% Drug addiction Alpha-beta-blocker drugs Patients with systemic diseases

Intervention groups
The intervention group will receive 0.2 mg clonidine orally with water and control group will receive placebo similar to first group half an hour before starting of surgery.

Main outcome variables
Evaluation of oral clonidine on hemodynamic changes such as systolic and diastolic blood pressure,MAP,heart rate,petco2 and spo2 ,pain ,shivering and nausea and vomiting.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140107016117N5**
Registration date: **2020-02-01, 1398/11/12**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-01, 1398/11/12**
Update count: **0**

Registration date
2020-02-01, 1398/11/12

Registrant information

Name
Bahman Naghipour Basmenj

Name of organization / entity
Tabriz Univesity of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-21, 1398/11/01

Expected recruitment end date
2020-06-21, 1399/04/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of premedication with oral clonidine on hemodynamics and recovery status of patients undergoing laparoscopic cholecystectomy

Public title

Effect of oral clonidine on hemodynamics and recovery status of patients undergoing laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All ASA I patients aged 20-65 years who are candidate for total elective laparoscopic cholecystectomy

Exclusion criteria:

Patients with systemic diseases(cardiovascular, pulmonary, liver and kidney,...) Blood loss over 10% Drug addiction Alpha-beta-blocker drugs

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study we use balanced randomization that at first four blocks with 9 combination will be formed and blocks will be numbered from 1to9. Compared to the simple randomization method, in this method the size of equilibrium of intervention and placebo groups will be established both during and at the end of study(randomization method is pre and post accidental blocks and will be done by randlist software)

Blinding (investigator's opinion)

Double blinded

Blinding description

The anesthesiologist who has responsible for the patients management of anesthesia will administer the medicine(s) via coded syringes had been prepared previously and will not aware of the injected drug(clonidine or placebo), and anesthesia nurse who is responsible for collection of patients information and study variables and is unaware of the administered drug will record the check- list during surgery and in the recovery.Also the patient is unaware of the injected medicine.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Faculity of Medicine, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2020-01-06, 1398/10/16

Ethics committee reference number

IR.TBZMED.REC.1398.1061

Health conditions studied

1

Description of health condition studied

The effect of oral clonidine on hemodynamic status and recovery after cholecystectomy surgery.

ICD-10 code

T88.59

ICD-10 code description

Other complications of anesthesia

Primary outcomes

1

Description

Systolic and diastolic blood pressure

Timepoint

From the beginning of anesthesia to 30th minute,every 5 minutes and after that every 15minutes and in recovery every 15 minutes until get out of recovery

Method of measurement

Mercury barometer

2

Description

Mean arterial pressure(MAP)

Timepoint

From the beginning of anesthesia to 30th minute,every 5 minutes and after that every 15minutes and in recovery every 15 minutes until get out of recovery

Method of measurement
Mercury barometer

3

Description
Heart rate
Timepoint
From the beginning of anesthesia to 30th minute,every 5 minutes and after that every 15minutes and in recovery every 15 minutes until get out of recovery
Method of measurement
Counting in each minutes

4

Description
Partial pressure of end tidal of carbondioxide
Timepoint
From the beginning of anesthesia and then every 30 minutes
Method of measurement
Using the Copnograph

5

Description
Saturation of peripheral oxygen
Timepoint
From the beginning of anesthesia and then every 30 minutes
Method of measurement
Via the Pulse Oximeter

Secondary outcomes

1

Description
pain
Timepoint
Every 15 minutes in recovery
Method of measurement
Visual analogue scale(VAS) as (0= non to 10= severe and unbearable pain)

2

Description
Severity of postoperative nausea and vomiting
Timepoint
Every 15 minutes in recovery
Method of measurement
Scoring by (0=non, 1=nausea, 2=vomiting, 3=vomiting >2 times)

3

Description
Severity of shivering
Timepoint
Every 15 minutes in recovery
Method of measurement
Observe and record the severity (shivering grade) and duration of shivering

Intervention groups

1

Description
Intervention group: The patients of this group will receive 0.2 mg clonidine orally with water .
Category
Treatment - Drugs

2

Description
Control group: this group will receive placebo similar to intervention group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza hospital
Full name of responsible person
Bahman Naghipour
Street address
Department of Anesthesiology, Faculty of Medical Sciences, Golgasht Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr Abolghasem Joyban
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Bahman Naghipour
Position
Consultant
Latest degree
Specialist
Other areas of specialty/work
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected deidentified IPD, IPD collected for the primary outcome measure are to be shared

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

Documents will be available for people working in academic institutions and also people working in businesses

Under which criteria data/document could be used

There will be no specific limitations to the utilization of the data

From where data/document is obtainable

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What processes are involved for a request to access data/document

Correspondence through email only

Comments