

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation of effects oral clonidine premedication on perioperative hemodynamic response and postoperative pain of patients with controlled hypertension undergoing laparoscopic cholecystectomy

Protocol summary

Summary

1) Objectives: Evaluation of effects oral clonidine premedication on perioperative hemodynamic response and postoperative pain of patients with controlled hypertension undergoing laparoscopic cholecystectomy
2) Design: in this randomized clinical trial we will assign 35 patients for each group randomly
3) Setting and Conduct: in this study, preoperatively, one group will receive oral clonidine and another group will receive oral placebo. One of our colleagues who is blinded to groups will gather and analyze the data.
4) Participants: Inclusion criteria: ASA grades II and III, both males and females, adult patients aged 18 to 65 years, with Controlled Hypertension (Systolic less than 140 and diastolic less than 90) scheduled Laparoscopic cholecystectomy surgeries. Exclusion criteria: Lack of patient consent, history of bronchial asthma, patients allergic to clonidine, hypertensive and diabetic patients, severe coronary insufficiency, recent myocardial infection, concomitant use of monoamine oxidase inhibitors, tricyclic antidepressants or opioids.
5) Interventions: In intervention group: patients received 0.2 mg oral Clonidine (CLONIDINE HCL 0.2MG TAB, Tolidaru, Iran) preoperatively and in Placebo Group: Patients received placebo tablets in the same shape of the clonidine tablets preoperatively.
6) Main Outcome Variable: Mean arterial blood pressure during the operation and Patient's postoperative pain intensity were evaluated. After collecting and recording data, SPSS program will use to analyze and evaluate the differences between the two groups of patients

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013120111398N5**

Registration date: **2014-02-16, 1392/11/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-02-16, 1392/11/27

Registrant information

Name

Mohammad Reza Ghodrati

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences, vice Chancellor for research affairs

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effects oral clonidine premedication on

perioperative hemodynamic response and postoperative pain of patients with controlled hypertension undergoing laparoscopic cholecystectomy

Public title

The effect of clonidine on hemodynamic complications of laparoscopy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: ASA grades II and III, both males and females, adult patients aged 18 to 65 years, with Controlled Hypertension (Systolic less than 140 and diastolic less than 90) scheduled Laparoscopic cholecystectomy surgeries. Exclusion criteria: Lack of patient consent, history of bronchial asthma, patients allergic to clonidine, hypertensive and diabetic patients, severe coronary insufficiency, recent myocardial infection, concomitant use of monoamine oxidase inhibitors, tricyclic antidepressants or opioids.

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Tehran University of Medical Sciences

Street address

Room 501, 5th Floor, Central Office of Tehran University of Medical Sciences, Keshavarz Bolvard

City

Tehran

Postal code

Approval date

2013-06-01, 1392/03/11

Ethics committee reference number

91/dal130/3493

Health conditions studied

1

Description of health condition studied

Laparoscopic cholecystectomy

ICD-10 code

K80.2

ICD-10 code description

Calculus of gallbladder without cholecystitis

Primary outcomes

1

Description

Mean arterial blood pressure

Timepoint

Before induction, in 1,5,10,15 and 20 minute after induction, and every 15 minute until the end of the operation

Method of measurement

Will be recorded by Automatic Hemodynamic Monitoring

Secondary outcomes

1

Description

Patient's pain intensity

Timepoint

Entrance to the recovery, 30, 60, 90 and 120 minutes postoperatively

Method of measurement

According to VAS rating score

Intervention groups

1

Description

In Intervention group: Patients received 0.2 mg oral Clonidine (CLONIDINE HCL 0.2MG TAB, Toliddaru, Iran) preoperatively.

Category

Prevention

2

Description

In Placebo Group: Patients received placebo tablets in the same shape of the clonidine tablets preoperatively.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Mohammad Reza Ghodrati MD.

Street address

Department of Anesthesia, Firoozgar Hospital, Beh-Afarin St. Karim Khan Av.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy, Iran University of Medical Sciences

Full name of responsible person

Dr Motavalian

Street address

5th floor, central bulding, Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research deputy, Iran 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

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Full name of responsible person

Mohammad Reza Ghodrati MD.

Position

Assistant Professor of Anesthesiology

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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