Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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, Toliddaru, 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 Ghodraty

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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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 Ghodraty 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 Siences

Full name of responsible person
Dr Motavalian

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

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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 Siences

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
Iran University of Medical Sciences

Full name of responsible person
Mohammad Reza Ghodraty MD.

Position
Assistant Professor of Anesthesiology

Other areas of specialty/work

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Web page address

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