Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the Effects of Oral Clonidine versus Oral Nifedipine on Hemodynamic Changes During Laparoscopic Cholecystectomy under General Anesthesia

Protocol summary

Summary

The aim of this study was determination and comparison the effects of oral clonidine versus oral nifedipine on hemodynamic changes during laparoscopic cholecystectomy under general anesthesia. In design of the study, 60 patients who were scheduled for elective laparoscopic cholecystectomy under general anesthesia were enrolled. The patients were divided into three equal groups randomly. Patients in the first group, received 150µg oral clonidine, in the second group, 10mg oral nifedipine and in the third group, they received vitamin C as a placebo. Method of general anesthesia was the same in the three groups. The participants of the study were patients in ASA class I-II between the age range of 20 and 60 years old. In the presence of patient refusal, systemic hypertension, congestive heart failure or aortic stenosis and also in the presence of positive history of antihypertensive, narcotic or sedative drugs consumption, patients were excluded from the study.

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Heart rate, systolic, diastolic and mean arterial blood pressure were measured and recorded before induction of anesthesia, before surgical incision, before carbon dioxide insufflation and then every 5 minutes until 75 minutes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305015471N1**
Registration date: **2013-08-03, 1392/05/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-08-03, 1392/05/12

Registrant information

Name

Seyed Abbas Hosseini Jahromi

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research of Qazvin University of Medical Sciences

Expected recruitment start date

2012-06-11, 1391/03/22

Expected recruitment end date
2013-03-15, 1391/12/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the Effects of Oral Clonidine versus Oral Nifedipine on Hemodynamic Changes During Laparoscopic Cholecystectomy under General Anesthesia

Public title
Effects of Clonidine and Nifedipine on Hemodynamic Changes due to Laparoscopic Cholecystectomy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: 1- Laparoscopic cholecystectomy 2- Age range between 20-60 years 3- ASA class I-II Exclusion criteria 1- Positive history of systemic hypertension, congestive heart failure and aortic stenosis 2- Positive history of antihypertensive, narcotic and sedative drugs consumption 3- Patient refusal 4- Operation time more than 2 hours
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double 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 Qazvin University of Medical Sciences
Street address
Shahid Bahonar Blvd, Qazvin University of Medical Sciences
City
Qazvin
Postal code
Approval date
2012-06-10, 1391/03/21
Ethics committee reference number
28/20/5938

Health conditions studied

1

Description of health condition studied
Cholecystitis
ICD-10 code
k80-K87
ICD-10 code description
Disorders of gallbladder and biliary tract in diseases classified elsewhere

Primary outcomes

1

Description
Blood pressure and heart rate after clonidine and nifedipine administration
Timepoint
Before induction of anesthesia, before surgical incision, before carbon dioxide insufflation and then every 5 minutes until the end of first hour of recovery period
Method of measurement
Noninvasive cardiovascular monitoring

Secondary outcomes

1

Description
Postoperative Pain
Timepoint
One hour after operation in recovery period and then for 24 hours in ward
Method of measurement
By Visual Analog Scale was determined and recorded in the questionnaire

2

Description
Shivering
Timepoint
One hour after operation in recovery period
Method of measurement
By observational method was determined and recorded in the questionnaire

3

Description

Nausea and vomiting

Timepoint

One hour after operation in recovery period

Method of measurement

By observational method was determined and recorded in the questionnaire

Intervention groups

1

Description

Patients in the first group, received 150µg oral clonidine (trademark Catapres, made in Tolid Darou Pharma Company in Iran) 30 minutes before induction of anesthesia

Category

Prevention

2

Description

Patients in the second group, received 10mg oral nifedipine (trademark Adalat, made in Tolid Darou Pharma Company in Iran) 30 minutes before induction of anesthesia

Category

Prevention

3

Description

Patients in the third group, received tablet of vitamin C (placebo) 30 minutes before induction of anesthesia

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Hospital

Full name of responsible person

Seyed Abbas Hosseini Jahromi M.D.

Street address

Padegan street, Shahid Rajaei Hospital

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research of Qazvin University of Medical Sciences

Full name of responsible person

Dr. Saeed Assefzadeh

Street address

Shahid Bahonar Blvd, Qazvin University of Medical Sciences

City

Qazvin

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-Chancellor for Research of Qazvin 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

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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