

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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. 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.

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)

Phone

+98 28 1333 6001

Email address

sahosseini@qums.ac.ir

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

Qazvin University of Medical Sciences

Full name of responsible person

Meisam Rezaei M.D.

Position

Resident in anesthesia

Other areas of specialty/work

Street address

Padegan Street, Shahid Rajaei Hospital, Qazvin

City

Qazvin

Postal code

Phone

+98 28 1332 0107

Fax

Email

rezaei.meisam@yahoo.co.uk

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyed Abbas Hosseini Jahromi M.D.

Position

Anesthesiologist / Associate Professor

Other areas of specialty/work

Street address

Padegan Street, Shahid Rajaei Hospital, Qazvin

City

Qazvin

Postal code

Phone

+98 28 1332 0107

Fax**Email**

sahosseini@qums.ac.ir papaya812002@yahoo.com

Web page address

+98 28 1223 6374

Fax**Email**

smhosseini@qums.ac.ir

parspaya872008@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Seyedeh Masoumeh Hosseini Valami M.D.

Position

Anesthesiologist / Associate Professor

Other areas of specialty/work**Street address**

Taleghani Street, Kowsar Hospital, Qazvin

City

Qazvin

Postal code**Phone****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