Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of oral clonidine on the shoulder tip pain and hemodynamic response of patients undergoing laparoscopic surgeries

Protocol summary

Summary

1) Objectives: To study the effect of oral clonidine on hemodynamic response and shoulder tip pain of patients undergoing laparoscopic surgeries. 2) Design: In this double blind (patients and researchers) randomized clinical trial we will assign 30 patients for each group randomly 3) Setting and Conduct: In this study, one group will receive oral clonidine and another group will receive oral placebo. 4) Participants: Inclusion criteria: ASA grades II and III, males and females, adult patients aged 18 to 65 years scheduled Laparoscopic surgeries. Exclusion criteria: Lack of patient consent, history of bronchial asthma, diabetes and hypertension, 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 before induction. Then, other doses of drug (0.2 mg) will prescribe after being awake and 6 hour after that and in Placebo Group: Patients received placebo tablets in the same shape of the clonidine tablets and the same times with intervention group.6) Main Outcome Variable: Mean arterial blood pressure and heart rates before prescribing Clonidine, doing induction and after 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: **IRCT2017071117468N4**
Registration date: **2017-08-16, 1396/05/25**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-08-16, 1396/05/25

Registrant information

Name
Meysam Hoseini Amiri
Name of organization / entity
Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 35 1824 0936
Email address
hoseiniam911@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences, vice Chancellor for research affairs

Expected recruitment start date

2017-03-25, 1396/01/05

Expected recruitment end date

2017-08-06, 1396/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral clonidine on the shoulder tip pain and hemodynamic response of patients undergoing laparoscopic surgeries

Public title

The effect of clonidine on the tip shoulder pain and

hemodynamic complications of laparoscopy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: ASA grades II and III, males and females, adult patients aged 18 to 65 years scheduled Laparoscopic surgeries. Exclusion criteria: Lack of patient consent, history of bronchial asthma, diabetes and hypertension, 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

N/A

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

Subjects will allocate to two equal groups of control and intervention using stratificaton randomization method.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd University of Medical Sciences

Street address

Headquarters of University, Bahonar square, Yazd

City

Yazd

Postal code

Approval date

2012-01-04, 1390/10/14

Ethics committee reference number

IR.SSU.REC.1390.125789

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

2

Description of health condition studied

Laparoscopic inguinal hernia repair

ICD-10 code

K40

ICD-10 code description

Inguinal hernia

Primary outcomes

1

Description

Patient's pain intensity

Timepoint

Just after awaking, 4, 8, 12, 24 hours after operation and time of patient's discharge.

Method of measurement

According to VAS rating score

Secondary outcomes

1

Description

Heart rates

Timepoint

Just before prescribing drug and induction, 4, 8, 12, 24 hours after operation and time of patient's discharge.

Method of measurement

Will be recorded by Automatic Hemodynamic Monitoring

2

Description

Mean arterial blood pressure

Timepoint

Just before prescribing drug and induction, 4, 8, 12, 24 hours after operation and time of patient's discharge.

Method of measurement

Will be recorded by Automatic Hemodynamic Monitoring

Intervention groups

1

Description

In control group: Patients received placebo tablets in the same shape of the clonidine tablets and the same times with intervention group.

Category

Placebo

2

Description
In intervention group: Patients received 0.2 mg oral Clonidine (CLONIDINE HCL 0.4MG TAB, Toliddaru, Iran) before induction. Then, other doses of drug (0.2 mg) will prescribe after being awake and 6 hour after that.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Behshti Hospital
Full name of responsible person
Seyed Nader Mostafavi
Street address
Shahid Beheshti Blvd, Taft, Yazd
City
Taft

2

Recruitment center
Name of recruitment center
Seyyed-Al-Shohada Hospital
Full name of responsible person
Morteza Managheb
Street address
Imam St, Yazd
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Yazd University of Medical Sciences
Full name of responsible person
Dr Fatemeh Ezadini
Street address
Headquarters of Medical University, Bahonar square, Yazd
City
Yazd
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, Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Dr Hamid Mirhosseini
Position
PhD of neuroscience/ Faculty membership
Other areas of specialty/work
Street address
Anesthesia department, Paramedical institue, Imam Hossein square, Yazd
City
Yazd
Postal code
Phone
+98 35 3624 5956
Fax
Email
Mirhoseini.h@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr Hamid Mirhosseini
Position
PhD of neuroscience/Faculty membership
Other areas of specialty/work
Street address
Anesthesia department, Paramedical institue, Imam Hossein square, Yazd
City
Yazd
Postal code
Phone
+98 35 3624 5956
Fax
Email
Mirhoseini.h@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Qom Medical Science University
Full name of responsible person

Meysam Hoseini Amiri
Position
MSc in nursing/ Faculty membership
Other areas of specialty/work
Street address
Qom University of Medical Sciences, Pardisan, Qom
City
Qom
Postal code
Phone
00
Fax
Email
hoseini_amiri@yahoo.com
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