

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

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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 stratification 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

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Anesthesia department, Paramedical institute, Imam Hossein square, Yazd

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Person responsible for scientific inquiries

Contact

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Dr Hamid Mirhosseini

Position

PhD of neuroscience/Faculty membership

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Qom Medical Science University

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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