

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparing the effect of oral clonidine and metoclopramide on intraoperative hemodynamic parameters, nausea, and vomiting after laparoscopic cholecystectomy

Protocol summary

Study aim

Comparing the effect of oral clonidine and metoclopramide on intraoperative hemodynamic parameters, nausea, and vomiting after laparoscopic cholecystectomy

Design

This randomized-controlled parallel, triple-blind clinical trial study, phase 3 will be conducted on 75 patients. The randomization will be done with a stratified block randomization method using random allocation software.

Settings and conduct

In this triple-blind clinical trial study, the patients undergoing elective laparoscopic cholecystectomy in Urmia Imam Khomeini hospital will be enrolled. Patients will be divided into interventions or placebo groups using stratified block randomization. Patients will receive oral clonidine 400 micrograms (group 1), oral metoclopramide 10 mg (group 2), and placebo (group 3) 90 minutes before induction.

Participants/Inclusion and exclusion criteria

In this study, the patients undergoing elective laparoscopic cholecystectomy with the physical status of one and two according to the American Society of Anesthesiology (ASA I and ASA II) and ages 20 to 60 years will be enrolled. The exclusion criteria will be including hypertension, diabetic patients, cardiovascular diseases, asthma disease, and allergy to clonidine and metoclopramide.

Intervention groups

Patients will receive oral clonidine 400 micrograms (group 1), oral metoclopramide 10 mg (group 2), and placebo (group 3) 90 minutes before induction.

Main outcome variables

The primary outcomes will be hemodynamic parameters and nausea and vomiting.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210919052515N4**

Registration date: **2022-04-12, 1401/01/23**

Registration timing: **prospective**

Last update: **2022-04-12, 1401/01/23**

Update count: **0**

Registration date

2022-04-12, 1401/01/23

Registrant information

Name

Naser Masoudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3337 9924

Email address

masoudi.n@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of oral clonidine and metoclopramide on intraoperative hemodynamic parameters, nausea, and vomiting after laparoscopic cholecystectomy

Public title

Evaluation of the effect of oral clonidine and metoclopramide after laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing elective laparoscopic cholecystectomy Patients with the physical status of one and two according to the American Society of Anesthesiology (ASA I and ASA II) Age 20 to 60 years

Exclusion criteria:

Hypertension Diabetic patients Cardiovascular diseases Asthma disease Allergy to clonidine and metoclopramide

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into intervention and placebo groups using stratified block randomization based on generated numbers by random allocation software. Firstly, patients will be stratified according to sex, and then randomization will be performed in each stratum. So that, in this software, the number of groups and the total number of the sample size will be entered firstly, and then in the block section, the block randomization method will be implemented. Patients will be allocated to intervention or placebo groups based on generated numbers.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The study will be conducted as a triple-blind clinical trial. The patient, the researcher who will be evaluating the outcomes, and the data Analyzer will be blinded to the intervention or placebo groups. The drugs will be given to the patient by a nurse in the ward. The names of the groups will be coded to the data analyzer.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Imam Khomeini university hospital- Urmia University of Medical Sciences

Street address

Imam Khomeini hospital., Ershad Ave., Modarres Blvd., Urmia., Iran.

City

Urmia

Province

West Azarbaijan

Postal code

57157-89397

Approval date

2021-11-17, 1400/08/26

Ethics committee reference number

IR.UMSU.HIMAM.REC.1400.019

Health conditions studied

1

Description of health condition studied

laparoscopic cholecystectomy

ICD-10 code

K91.5

ICD-10 code description

Postcholecystectomy syndrome

Primary outcomes

1

Description

Heart rate

Timepoint

During induction, 5 minutes, 10 minutes after intubation, during skin incision, 15 and 30 minutes after pneumonia, 30 minutes after pneumonia release

Method of measurement

Monitoring

2

Description

Systolic blood pressure

Timepoint

During induction, 5 minutes, 10 minutes after intubation, during skin incision, 15 and 30 minutes after pneumonia, 30 minutes after pneumonia release

Method of measurement

Monitoring

3

Description

Diastolic blood pressure

Timepoint

During induction, 5 minutes, 10 minutes after intubation, during skin incision, 15 and 30 minutes after pneumonia, 30 minutes after pneumonia release

Method of measurement

Monitoring

4

Description

Mean arterial pressure (MAP)

Timepoint

During induction, 5 minutes, 10 minutes after intubation, during skin incision, 15 and 30 minutes after pneumonia, 30 minutes after pneumonia release

Method of measurement

Monitoring

5

Description

Nausea

Timepoint

At the end of surgery

Method of measurement

Yes/No

6

Description

Vomiting

Timepoint

At the end of surgery

Method of measurement

Yes/No

Secondary outcomes

1

Description

Complications

Timepoint

At the end of surgery

Method of measurement

Clinical examination

Intervention groups

1

Description

Intervention group: Patients will receive one tablet of oral clonidine of 200 micrograms (group 1), 90 minutes before induction. Clonidine will be provided by Tolid Darou pharmaceutical company.

Category

Treatment - Other

2

Description

Intervention group: Patients will receive one tablet of oral metoclopramide 10 mg (group 2), 90 minutes before induction. metoclopramide will be provided by Amin Pharmaceutical Company.

Category

Treatment - Other

3

Description

Control group: Patients will receive placebo (group 3) 90 minutes before induction.

Category

Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Imam Khomeini hospital

Full name of responsible person

Dr. Naser Masoudi

Street address

Imam Khomeini hospital., Ershad Ave., Modarres Blvd., Urmia., Iran.

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Email

masoudi.n@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Dr.Saber Gholizadeh

Street address

Urmia University of Medical Sciences, Resalat street, Jihad Blvd., Urmia, Iran.

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gholizadeh.s@umsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Naser Masoudi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Confidentiality of patient information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The results of the study will be published as an article.

When the data will become available and for how long

After publishing the article

To whom data/document is available

Researchers

Under which criteria data/document could be used

The results will be published as an article and the data will not be published.

From where data/document is obtainable

corresponding author

What processes are involved for a request to access data/document

By email address of the corresponding author:
masoudi.n@umsu.ac.ir

Comments