

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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.

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

57157-89397

**Phone**

+98 44 3345 7286

**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.

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5714783734

**Phone**

+98 44 3223 3009

**Email**

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

**Street address**

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

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

57157-89397

**Phone**

+98 44 3345 7286

**Email**

masoudi.n@umsu.ac.ir

**Person responsible for scientific 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

**Street address**

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

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

57157-89397

**Phone**

+98 44 3345 7286

**Email**

masoudi.n@umsu.ac.ir

**Person responsible for updating data**

**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

**Street address**

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

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

57157-89397

**Phone**

+98 44 3345 7286

**Email**

masoudi.n@umsu.ac.ir

**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**