

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of premedication with oral clonidine on hemodynamics and recovery status of patients undergoing laparoscopic cholecystectomy

#### Protocol summary

##### Study aim

Effect of premedication with oral clonidine on hemodynamics and recovery status of patients undergoing laparoscopic cholecystectomy.

##### Design

120 patients that meet the inclusion criteria after surgery finished and the patient is discharged from anesthesia will be selected as research sample and then divided into intervention and control groups with binary blocking. The intervention group will receive clonidine and the control group will receive placebo. The study is a randomized, double-blind, placebo-controlled clinical trial.

##### Settings and conduct

Patients in operation room of Imam Reza hospital will be randomly divided into two groups according to the random number table. The intervention group received 0.5 mg clonidine and the control group will receive the same amount of placebo half an hour before surgery. Given that the study is double-blind. Both clonidine and placebo medications will be prepared each morning by the number of surgeries and number required by the plan's administrator. Envelope A contains oral clonidine and envelope B is a placebo. Each patient will receive the envelopes based on whether they are A or B coded by an anesthetist who is blinded of the type of drug. In this study patient and anesthesiologist is blinded.

##### Participants/Inclusion and exclusion criteria

Entry requirements: All ASA I patients aged 20-65 years who are candidate for laparoscopic cholecystectomy.  
Exclusion criteria: Blood loss over 10% Drug addiction  
Alpha-beta-blocker drugs Patients with systemic diseases

##### Intervention groups

The intervention group will receive 0.2 mg clonidine orally with water and control group will receive placebo similar to first group half an hour before starting of surgery.

##### Main outcome variables

Evaluation of oral clonidine on hemodynamic changes such as systolic and diastolic blood pressure, MAP, heart

rate, petco<sub>2</sub> and spo<sub>2</sub>, pain, shivering and nausea and vomiting.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140107016117N5**

Registration date: **2020-02-01, 1398/11/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-02-01, 1398/11/12**

Update count: **0**

##### Registration date

2020-02-01, 1398/11/12

##### Registrant information

##### Name

Bahman Naghipour Basmenj

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3337 3950

##### Email address

naghipourb@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-21, 1398/11/01

##### Expected recruitment end date

2020-06-21, 1399/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Effect of premedication with oral clonidine on hemodynamics and recovery status of patients undergoing laparoscopic cholecystectomy

**Public title**  
Effect of oral clonidine on hemodynamics and recovery status of patients undergoing laparoscopic cholecystectomy

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
All ASA I patients aged 20-65 years who are candidate for total elective laparoscopic cholecystectomy  
**Exclusion criteria:**  
Patients with systemic diseases(cardiovascular, pulmonary, liver and kidney,...) Blood loss over 10% Drug addiction Alpha-beta-blocker drugs

**Age**  
From **20 years** old to **65 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**  
Target sample size: **120**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study we use balanced randomization that at first four blocks with 9 combination will be formed and blocks will be numbered from 1to9. Compared to the simple randomization method, in this method the size of equilibrium of intervention and placebo groups will be established both during and at the end of study(randomization method is pre and post accidental blocks and will be done by randlist software)

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The anesthesiologist who has responsible for the patients management of anesthesia will administer the medicine(s) via coded syringes had been prepared previously and will not aware of the injected drug(clonidine or placebo ), and anesthesia nurse who is responsible for collection of patients information and study variables and is unaware of the administered drug will record the check- list during surgery and in the recovery.Also the patient is unaware of the injected medicine.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

Faculty of Medicine, Golgasht Street

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614766

#### Approval date

2020-01-06, 1398/10/16

#### Ethics committee reference number

IR.TBZMED.REC.1398.1061

## Health conditions studied

### 1

#### Description of health condition studied

The effect of oral clonidine on hemodynamic status and recovery after cholecystectomy surgery.

#### ICD-10 code

T88.59

#### ICD-10 code description

Other complications of anesthesia

## Primary outcomes

### 1

#### Description

Systolic and diastolic blood pressure

#### Timepoint

From the beginning of anesthesia to 30th minute,every 5 minutes and after that every 15minutes and in recovery every 15 minutes until get out of recovery

#### Method of measurement

Mercury barometer

### 2

#### Description

Mean arterial pressure(MAP)

#### Timepoint

From the beginning of anesthesia to 30th minute,every 5 minutes and after that every 15minutes and in recovery every 15 minutes until get out of recovery

### **Method of measurement**

Mercury barometer

### **3**

#### **Description**

Heart rate

#### **Timepoint**

From the beginning of anesthesia to 30th minute, every 5 minutes and after that every 15 minutes and in recovery every 15 minutes until get out of recovery

#### **Method of measurement**

Counting in each minutes

### **4**

#### **Description**

Partial pressure of end tidal of carbondioxide

#### **Timepoint**

From the beginning of anesthesia and then every 30 minutes

#### **Method of measurement**

Using the Copnograph

### **5**

#### **Description**

Saturation of peripheral oxygen

#### **Timepoint**

From the beginning of anesthesia and then every 30 minutes

#### **Method of measurement**

Via the Pulse Oximeter

## **Secondary outcomes**

### **1**

#### **Description**

pain

#### **Timepoint**

Every 15 minutes in recovery

#### **Method of measurement**

Visual analogue scale(VAS) as (0= non to 10= severe and unbearable pain)

### **2**

#### **Description**

Severity of postoperative nausea and vomiting

#### **Timepoint**

Every 15 minutes in recovery

#### **Method of measurement**

Scoring by (0=non, 1=nausea, 2=vomiting, 3=vomiting >2 times)

### **3**

#### **Description**

Severity of shivering

#### **Timepoint**

Every 15 minutes in recovery

#### **Method of measurement**

Observe and record the severity (shivering grade) and duration of shivering

## **Intervention groups**

### **1**

#### **Description**

Intervention group: The patients of this group will receive 0.2 mg clonidine orally with water .

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Control group: this group will receive placebo similar to intervention group

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Emam Reza hospital

##### **Full name of responsible person**

Bahman Naghipour

##### **Street address**

Department of Anesthesiology, Faculty of Medical Sciences, Golgasht Street

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##### **Email**

naghipourb@tbzmed.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Dr Abolghasem Joyban

##### **Street address**

Vice chancellor for research, Daneshgah street, Tabriz

##### **City**

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research-vice@tbzmed.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Bahman Naghipour

**Position**

Consultant

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**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**  
Yes - There is a plan to make this available  
**Data Dictionary**  
Yes - There is a plan to make this available  
**Title and more details about the data/document**  
All collected deidentified IPD, IPD collected for the primary outcome measure are to be shared  
**When the data will become available and for how long**  
Starting 6 months after publication  
**To whom data/document is available**

Documents will be available for people working in academic institutions and also people working in businesses  
**Under which criteria data/document could be used**  
There will be no specific limitations to the utilization of the data  
**From where data/document is obtainable**  
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**What processes are involved for a request to access data/document**  
Correspondence through email only  
**Comments**