

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of pneumoperitoneum-induced hypertension during laparoscopic cholecystectomy under general anesthesia on postoperative pain compared with normal blood pressure induced by intravenous nitroglycerin

#### Protocol summary

##### Study aim

Comparison of pain after laparoscopic cholecystectomy between hypertension during surgery due to pneumoperitoneum and normal intraoperative hypertension induced by intravenous nitroglycerin

##### Design

Two arms parallel-group randomized clinical trial with blinded postoperative care and outcome assessment. In this study, we use the block randomization method

##### Settings and conduct

ASA1(American Society of Anesthesiology) patients who are scheduled for laparoscopic cholecystectomy refer to Firoozgar hospital are randomly assigned to higher blood pressure ( group A : MAP (Mean Arterial Pressure) increases up to 20% higher than baseline MAP) and lower blood pressure ( group B : MAP reduces to 20% lower than baseline MAP) The pain intensity in hours 2, 8, 12 and 24 after surgery and also the total dose of analgesics used to manage postoperative pain are recorded and compare between two groups. In this study, the clinical caregiver and statistical analyst are blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criterias: Patients aged 20 to 60 yrs without underlying disorders ( ASA1) who are scheduled for laparoscopic cholecystectomy. Exclusion criterias: patients using any analgesic drugs during recent week.

##### Intervention groups

Intervention group :The intervention of this study is pneumoperitoneum-induced hypertension in cholecystectomy surgery, which causes postoperative pain. Control group :Normal blood pressure induced by intravenous nitroglycerin injection and control or reduction of postoperative pain

##### Main outcome variables

Blood pressure and Heart rate during surgery Pain score

after surgery Meperidine dosage after surgery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210607051501N1**

Registration date: **2021-10-24, 1400/08/02**

Registration timing: **retrospective**

Last update: **2021-10-24, 1400/08/02**

Update count: **0**

##### Registration date

2021-10-24, 1400/08/02

##### Registrant information

##### Name

Ali Khatibi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8856 7458

##### Email address

khatibi.al@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-07-23, 1400/05/01

##### Expected recruitment end date

2021-10-22, 1400/07/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of pneumoperitoneum-induced hypertension during laparoscopic cholecystectomy under general anesthesia on postoperative pain compared with normal blood pressure induced by intravenous nitroglycerin

**Public title**

The effect of hypertension due to cholecystectomy surgery on postoperative pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

No underlying disorders (ASA 1) Aged between 20 to 60 yr

**Exclusion criteria:**

Having analgesic agent during last week

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Care provider
- Data analyser

**Sample size**

Target sample size: **85**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, we use the block randomization method so that after selecting patients according to the inclusion and exclusion criteria by selecting numbers from the table of random numbers and adapting to the blocks, patients are divided into study groups. To randomize the two treatment methods, we create 4 blocks in six different states, then select a number using the table of numbers, and determine the study groups by matching the numbers with the blocks. For example, if the first digit of our number is 1 to 6, select a block and the division is done, but if, for example, our number is 94071, the digit 9 is not valid and we select the next digit. Here, based on the block 4, we divide patients into groups. 1. TTCC 2. TCTC 3. TCCT 4. CCTT 5. CTCT 6. CTTC

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, people who are responsible for patient care and analysis of statistical data do not know about the treatment process and study groups, and information is provided to them in groups A and B.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

**Street address**

Firoozgar hospital, Behafarin st., Karimkhan-e-zand st., Vali\_Asr sq

**City**

Tehran

**Province**

Tehran

**Postal code**

1593747811

**Approval date**

2020-05-10, 1399/02/21

**Ethics committee reference number**

IR.IUMS.FMD.REC.1399.116

**Health conditions studied****1****Description of health condition studied**

Cholecystitis

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Postoperative pain score

**Timepoint**

The postoperative pain intensity (VAS) will record in hours 2, 8, 12 and 24 after surgery.

**Method of measurement**

Visual Analogue Scale

**2****Description**

Pethedine dosage after surgery

**Timepoint**

The total dose of pethedine used for pain control will record in hours 2, 8, 12 and 24 after surgery

**Method of measurement**

Data record forms

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The intervention group includes patients who meet the inclusion criteria and undergo laparoscopic cholecystectomy. The intervention is surgery-induced pneumoperitoneum, which increases intraoperative blood pressure and postoperative pain. To clarify the hypothesis, the patient's blood pressure is measured at different times during the operation and its effect on postoperative pain is recorded at different times. The induced gas pressure is in the range of 14 to 16 cm of water.

#### Category

Treatment - Other

### 2

#### Description

Control group: In the control group, patients who meet the inclusion criteria and undergo laparoscopic cholecystectomy are included. In these patients, by injecting nitroglycerin (Manufactured by Caspianamin Pharmaceutical Company) at a dose of 5 to 10 micrograms per minute with micro Burette Infusion Set until the patient reaches normal blood pressure and records it at different times during the operation, the amount of postoperative pain is recorded at different times.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Firoozgar hospital

##### Full name of responsible person

Ali Khatibi

##### Street address

Firoozgar hospital, Behafarin st., Karimkhan-e-zand st., Vali\_asr sq.

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Ali Khatibi

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Firoozgar hospital, Behafarin st., Karimkhan-e-zand st., Vali-asr sq.,

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#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Iran 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

Iran University of Medical Sciences

##### Full name of responsible person

Ali Khatibi

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Ali Khatibi  
**Position**  
Associate professor  
**Latest degree**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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 datas could be shared after unidentification of the participants.

### When the data will become available and for how long

6 months after publication

### To whom data/document is available

The results and datas would be available for everybody

### Under which criteria data/document could be used

No limitation

### From where data/document is obtainable

The main author Dr Ali Khatibi, email address  
khatibi.al@iums.ac.ir

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

Sending the request, assessment the request by the author of this study

### Comments