

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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 updating data

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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