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
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Iran (Islamic Republic of)
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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 Caspiantamin 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

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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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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