Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

"Comparison of the Effect of Intrá-Abdominal Pressure on Hemodynamic Parameters and Cerebral Oxygenation during Elective Laparoscopic Cholecystectomy in Elderly Patients under General Anesthesia ; A Double Blind Clinical Trial Study"

Protocol summary

Study aim

Comparison of the effect of intra-abdominal pressures on hemodynamic parameters and cerebral oxygenation during laparoscopic cholecystectomy surgery in elderly patients under general anesthesia.

Design

Clinical trial, two parallel groups, two blind strains, randomized, on 31 patients in each group, to generate a random sequence in this clinical trial, WinPepi software and allocation concealment method will be used.

Settings and conduct

The study will be conducted in the Razi Teaching Hospital in Rasht. Patients are randomly divided into two groups: high intra-abdominal pressure (13-15 liters per minute) and low intra-abdominal pressure (10-12 liters per minute). Two groups are compared. The surgeon and the anesthesiologist who is responsible for the evaluation and data collection will be unaware of the intra-abdominal pressure applied to the patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: elderly patients over 60 years old with ASA class 1-2 candidates for elective laparoscopic cholecystectomy Exclusion criteria: patients with cerebrovascular disease (cerebral ischemia or hematoma), neurological disorders (dementia, seizures, Parkinson's and Alzheimer's), uncontrolled hypertension and diabetes, advanced organ failure (class 3 and 4 heart failure), patient refusal to participate in the study Body mass index above 35 and below 18

Intervention groups

high intra-abdominal pressure (13-15 mm Hg) ;low intra-abdominal pressure (10-12 mm Hg).

Main outcome variables

Cerebral oxygenation percentage; systolic, diastolic and mean arterial blood pressure; heart rate; Oxygen saturation of arterial blood; carbon dioxide at the end of exhalation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240718062454N1**
Registration date: **2024-08-01, 1403/05/11**
Registration timing: **prospective**

Last update: **2024-08-01, 1403/05/11**
Update count: **0**

Registration date

2024-08-01, 1403/05/11

Registrant information

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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

2024-09-22, 1403/07/01

Expected recruitment end date

2025-09-23, 1404/07/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
"Comparison of the Effect of Intrā-Abdominal Pressure on Hemodynamic Parameters and Cerebral Oxygenation during Elective Laparoscopic Cholecystectomy in Elderly Patients under General Anesthesia ; A Double Blind Clinical Trial Study"

Public title
"Investigating Intra-abdominal Pressures on Elderly Patients during Elective Laparoscopic Cholecystectomy"
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Elderly patients over 60 years old with ASA class 1-2 are candidates for elective laparoscopic cholecystectomy.
Exclusion criteria:
Patients with cerebrovascular disease (cerebral ischemia or hematoma), neurological disorders (dementia, seizures, Parkinson's and Alzheimer's), uncontrolled hypertension and diabetes, advanced organ failure (class 3 and 4 heart failure) Patient refusal to participate in the study Body mass index above 35 and below 18
Age
From **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **31**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are assigned to two groups of high intra-abdominal pressure (13-15 mm Hg) and low intra-abdominal pressure (10-12 mm Hg) using the random sequence created in blocks of four by WinPepi software. Allocation concealment will be used for concealment. This method is used to implement the random sequence of participants in the study. So that before assigning the individual, the assigned group is not specified. In this method, using identical sealed envelopes, with a random sequence, in this method, each of the random sequences created is recorded on a card, and the cards are placed inside the envelopes in order. In order to maintain the random sequence, the outer surface of the envelopes is numbered in the same order. At the time of placement of eligible patients for the study on the bed of the operating room, one of the envelopes is opened by the surgical technician responsible for adjusting the pressure of the laparoscope and placed in one of the two groups of high and low intra-abdominal pressure based on the pressure recorded in the patient card. Patients will be randomized with the help of four random blocks created by the computer (Win Pepi 11.65 software) by an experienced surgical technician who is not a collaborator of the project through the list of eligible patients who have given informed consent and the sequence of randomization blocks to 1:1 ratio are assigned to one of the two groups of high intra-abdominal pressure (13-15 mm Hg) and low intra-abdominal pressure (10-12 mm Hg).
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is double-blind. The surgeon and the anesthesiologist, who is responsible for evaluating and collecting data, will be unaware of the intra-abdominal pressure applied to the patient, and the adjustment of the intra-abdominal pressure will be performed by an experienced surgical technician who is not a member of the project. . The anesthesiologist in charge of the patient will be informed about the treatment groups in order to take the necessary measures in case of complications. In order to blind the surgeon, the intra-abdominal pressure monitor of the laparoscope device is placed outside the view of the surgeon and exposed to the view of the surgical technician responsible for adjusting the patient's intra-abdominal pressure.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Anesthesiology Research Center , Alzahra Hospital, Guilan University of Medical Sciences, Namjoo Street, Rasht, Iran
City
Rasht
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Guilan
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4144654839
Approval date
2024-06-26, 1403/04/06
Ethics committee reference number
IR.GUMS.REC.1403.148

Health conditions studied

1

Description of health condition studied
Intraabdominal pressure
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Hemodynamic parameters
ICD-10 code
ICD-10 code description

3

Description of health condition studied
cerebral oxygenation
ICD-10 code
ICD-10 code description

4

Description of health condition studied
Elective laparoscopic cholecystectomy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The amount of brain oxygen of patients
Timepoint
In the awake state (T0), 5 minutes after induction of anesthesia and intubation before Blowing gas into the abdomen (T1) and then 5 minutes after blowing gas into the abdomen (T2), 15 minutes after blowing gas into the abdomen (T3), immediately after gas exit and changing the horizontal position (T5) And it will be recorded 15 minutes after the exit of gas (T6).
Method of measurement
It will be measured based on the cerebral oxygenation percentage listed in the patient's monitoring.

2

Description
Systolic, diastolic and mean arterial blood pressure
Timepoint
In the awake state (T0), 5 minutes after induction of anesthesia and intubation before Blowing gas into the abdomen (T1) and then 5 minutes after blowing gas into the abdomen (T2), 15 minutes after blowing gas into the abdomen (T3), immediately after gas exit and changing the horizontal position (T5) And it will be recorded 15 minutes after the exit of gas (T6).
Method of measurement
Based on the blood pressure listed in the patient's monitoring, it will be measured in millimeters of mercury.

3

Description
The patient's heart rate
Timepoint
In the awake state (T0), 5 minutes after induction of anesthesia and intubation before blowing gas into the abdomen (T1) and then 5 minutes after blowing gas into the abdomen (T2), 15 minutes after blowing gas into the abdomen Abdomen (T3) will be recorded immediately after passing gas and changing the horizontal position (T5) and 15 minutes after passing gas (T6).
Method of measurement
It will be measured based on the number of beats listed in the patient's monitoring based on the number of heart beats per minute.

4

Description
Oxygen saturation of arterial blood of patients
Timepoint
In the awake state (T0), 5 minutes after induction of anesthesia and intubation before blowing gas into the abdomen (T1) and then 5 minutes after blowing gas into the abdomen (T2), 15 minutes after blowing gas into the abdomen Abdomen (T3) will be recorded immediately after passing gas and changing the horizontal position (T5) and 15 minutes after passing gas (T6).
Method of measurement
It will be measured based on the arterial oxygenation percentage listed in the patient monitoring.

5

Description
End-expiratory carbon dioxide
Timepoint
In the awake state (T0), 5 minutes after induction of anesthesia and intubation before blowing gas into the abdomen (T1) and then 5 minutes after blowing gas into the abdomen (T2), 15 minutes after blowing gas into the abdomen Abdomen (T3) will be recorded immediately after passing gas and changing the horizontal position (T5) and 15 minutes after passing gas (T6).
Method of measurement
Based on the exhaled carbon dioxide listed in the patient's monitoring, it will be measured in millimeters of mercury.

Secondary outcomes

1

Description
Investigation of complications and outcome of patients in recovery in two groups of high intra-abdominal pressure (13-15 mm Hg) and low intra-abdominal pressure (10-12 mm Hg)
Timepoint
After surgery
Method of measurement
The presence of nausea,

vomiting/hemorrhage/pneumothorax/loss of saturation/increase or decrease in blood pressure will be measured in patients.

2

Description
Satisfaction of the surgeon
Timepoint
After surgery
Method of measurement
Based on the 5-point Likert scale, it will be measured as very poor/poor/satisfactory/good/excellent.

Intervention groups

1

Description
Intervention group: High intra-abdominal pressure (13-15 mmHg)
Category
Treatment - Surgery

2

Description
Intervention group: High intra-abdominal pressure (13-15 mmHg)
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Medical Education Center
Full name of responsible person
Somayeh Sayad Nouri
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Rasht 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
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Position
Assistant Professor of Anesthesiology
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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
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

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

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