Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of BMI-adjusted positive end-expiratory pressure versus zero positive end-expiratory pressure on optic nerve sheath diameter measured by ultrasonography in adults undergoing elective laparoscopic cholecystectomy

Protocol summary

Study aim

To evaluate the effect of positive end expiratory pressure on ultrasonographic optic nerve sheath diameter, as a surrogate marker of intracranial pressure, in adults undergoing elective laparoscopic cholecystectomy under general anesthesia.

Design

Single center, parallel group, randomized controlled, double blind clinical trial with 50 participants allocated equally by computer generated block randomization using sealed envelopes.

Settings and conduct

The trial will be conducted at a tertiary hospital called "Iraqi hospital" in Kufa. Participants will undergo standard general anesthesia and laparoscopic cholecystectomy. Participants, outcome assessor, and data analyst will remain blinded. Group allocation will be concealed using sequentially numbered opaque sealed envelopes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adults aged 18 to 70 years, with American Society of Anesthesiologists physical status I to III, undergoing elective laparoscopic cholecystectomy. Exclusion criteria: ophthalmic disease, cerebrovascular disease, significant respiratory disease, pregnancy, inability to undergo optic nerve sheath ultrasonography, refusal to participate.

Intervention groups

Control group receives volume controlled ventilation with zero positive end expiratory pressure. Intervention group receives body mass index adjusted positive end expiratory pressure of 5, 8, or 10 centimeters of water.

Main outcome variables

Primary outcome is optic nerve sheath diameter measured by ultrasonography. Secondary outcomes are mean arterial pressure, heart rate, peak inspiratory pressure, plateau pressure, driving pressure, and their association with optic nerve sheath diameter.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260627069955N1**
Registration date: **2026-08-01, 1405/05/10**
Registration timing: **prospective**

Last update: **2026-08-01, 1405/05/10**
Update count: **0**

Registration date

2026-08-01, 1405/05/10

Registrant information

Name

Muslim Ghali Yousef Al-Tamimi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

muslimghaly@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-03, 1405/06/12

Expected recruitment end date

2026-12-03, 1405/09/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of BMI-adjusted positive end-expiratory pressure versus zero positive end-expiratory pressure on optic nerve sheath diameter measured by ultrasonography in adults undergoing elective laparoscopic cholecystectomy

Public title

The effect of positive end-expiratory pressure (PEEP) on optic nerve sheath diameter during laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults aged 18–65 years. ASA physical status I–III. Scheduled for elective laparoscopic cholecystectomy under general anesthesia. Ability to provide written informed consent. Eligible for volume-controlled mechanical ventilation during surgery.

Exclusion criteria:

History of acute or chronic ophthalmic disease (e.g., glaucoma, optic neuritis, retinal disease, previous ocular surgery affecting ONSD measurement). Known cerebrovascular or neurological disease associated with altered intracranial pressure (such as stroke, intracranial tumor, hydrocephalus, traumatic brain injury). Significant respiratory disease (such as COPD, severe asthma, restrictive lung disease) that may influence ventilatory management. Contraindications to laparoscopic surgery or pneumoperitoneum. Inability to obtain adequate ultrasonographic visualization of the optic nerve sheath. Pregnancy.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomized in a 1:1 ratio into either the control group (0 cmH_2O PEEP) or the PEEP group using block randomization with a fixed block size of four. The unit of randomization will be the individual patient. No stratification will be applied. The randomization sequence will be generated by an independent investigator using a computer-based random number generator (IBM SPSS Statistics version 26). The sequence will be created before patient enrollment and will consist of randomly permuted blocks to ensure balanced allocation between the two groups throughout the recruitment period. Allocation concealment will be maintained using sequentially numbered, opaque, sealed envelopes prepared by a researcher not involved in patient recruitment, anesthesia management, outcome assessment, or statistical analysis. Immediately before induction of anesthesia, the attending anesthesiologist will open the next envelope in sequence to determine group assignment. Thus, allocation concealment will be carried out until the moment of assignment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will be blinded to group allocation and will not be informed whether they receive zero PEEP or BMI-adjusted PEEP during mechanical ventilation. The attending anesthesiologist responsible for intraoperative ventilator management cannot be blinded because adjustment of PEEP is required according to the assigned intervention. However, this anesthesiologist will have no role in outcome assessment, data collection, or statistical analysis. The ultrasonographer who performs all optic nerve sheath diameter (ONSD) measurements, the investigators responsible for collecting perioperative data, and the data analyst will remain blinded to treatment allocation throughout the study. Group allocation will be concealed using sequentially numbered, opaque, sealed envelopes prepared by an independent researcher. The envelopes will be opened only after patient enrollment and immediately before the induction of anesthesia. Study data will be be coded before statistical analysis so that the data analyst remains unaware of group assignments until completion of the final analysis. No Data and Safety Monitoring Board (DSMB) is planned because of the small sample size and the low-risk nature of the study. Manuscript preparation will be based on coded data after completion of the analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of the School of Medicine, Shahid Beheshti University of Medical Sciences

Street address

Third floor, School of Medicine, next to Taleghani Hospital, Evin, Shahid Chamran Highway

City
Tehran
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Postal code
19839-63113
Approval date
2026-06-02, 1405/03/12
Ethics committee reference number
IR.SBMU.MSP.REC.1405.162

Health conditions studied

1

Description of health condition studied
Symptomatic cholelithiasis requiring elective laparoscopic cholecystectomy
ICD-10 code
Z90.4
ICD-10 code description
Acquired absence of other specified parts of digestive tract

Primary outcomes

1

Description
Optic nerve sheath diameter measured by ultrasonography
Timepoint
Before induction of anesthesia, immediately after tracheal intubation, 5 minutes after pneumoperitoneum, 5 minutes after positive end expiratory pressure application, 5 minutes after peritoneal deflation, and 5 minutes after tracheal extubation.
Method of measurement
Measurement of optic nerve sheath diameter by orbital ultrasonography using a seven point five megahertz linear ultrasound probe, with measurements obtained from both eyes at three millimeters behind the optic disc.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will receive volume controlled mechanical ventilation with positive end expiratory pressure applied 5 minutes after pneumoperitoneum according to body mass index. Patients with body mass index less than 25 kilograms per square meter will receive 5 centimeters of water positive end expiratory pressure, those with body mass index 25 to 30 kilograms per square meter will receive 8 centimeters of water, and those with body mass index greater than 30 kilograms per square meter will receive 10 centimeters of water. Ventilation will be maintained with a tidal volume of 6 milliliters per kilogram of ideal body weight throughout surgery.
Category
Other

2

Description
Control group: Patients will receive standard volume controlled mechanical ventilation with zero positive end expiratory pressure throughout surgery. Ventilator settings, including tidal volume of 6 milliliters per kilogram of ideal body weight, respiratory rate adjusted to maintain end tidal carbon dioxide between 35 and 40 millimeters of mercury, inspiratory to expiratory ratio of 1 to 2, and inspired oxygen fraction of 0.5, will be identical to the intervention group. No positive end expiratory pressure will be applied.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Iraqi Hospital
Full name of responsible person
Muslim Ghali Yousef
Street address
Iraqi hospital, Next to to Al-Furat Hospital, Sahla street, Kufa, Najaf
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Ali Ziayi
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Third floor, School of Medicine, next to Taleghani Hospital, Evin, Shahid Chamran Highway
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Firoozeh Madadi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Next to Shahid Beheshti University of Medical Sciences, Shahid A'rabi Street, Yemen Street, Shahid Chamran Highway

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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

Data regarding ultrasonography of patients will be available.

When the data will become available and for how long

After data collection completion

To whom data/document is available

Other researchers

Under which criteria data/document could be used

Belonging to academic institution

From where data/document is obtainable

researcher's personal email fmadadi33@gmail.com

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

Requesting by email

Comments