Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

“Individualized Versus Fixed Positive End- Expiratory Pressure (PEEP) in patients Undergoing Laparoscopic Surgery ”

Protocol summary

Study aim

This study aims to compare individualized positive end-expiratory pressure (PEEP) with fixed PEEP in improving intraoperative oxygenation, respiratory mechanics, and postoperative pulmonary outcomes in patients undergoing elective laparoscopic surgery.

Design

this is a two-arm, parallel-group, prospeective randomized controlled clinical trial. a total of 96 eligible participants will be recuited using consective sampling and randomly allocated in a 1:1 ratio into two groups individualized PEEP (n=48)and fixed PEEP (n=48) randomization will be performed using computer-generated randomization sequence. Allocation concealment will be maintained using sealed opaque envelopes.

Settings and conduct

study will be conducted in patients undergoing laparoscopic surgery under general anesthesia Eligible patients fulfilling the inclusion criteria will be recruited consecutively until the required sample size is achieved. After obtaining informed consent, participants will be randomly allocated to either the Fixed PEEP group (5 cmH_2O) or the Individualized PEEP.

Participants/Inclusion and exclusion criteria

Inclusion Criteria Patients aged 20–65 years. ASA physical status I–III. Exclusion Criteria Patients with progressive neuromuscular disease. Known difficult airway.

Intervention groups

Individualized PEEP Group (Group B): Following induction of anesthesia and establishment of pneumoperitoneum, a recruitment maneuver will be performed. Recruitment maneuver will be standardized. Fixed PEEP Group (Group A): Patients will receive a fixed PEEP of 5 cmH_2O throughout the surgical procedure.

Main outcome variables

To compare the effect of individualized PEEP versus fixed PEEP on intraoperative oxygenation (PaO_2/FiO_2 ratio) in patients undergoing laparoscopic surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260916071083N1**
Registration date: **2026-09-30, 1405/07/08**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-30, 1405/07/08**
Update count: **0**

Registration date

2026-09-30, 1405/07/08

Registrant information

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-14, 1405/05/23

Expected recruitment end date

2026-12-14, 1405/09/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
"Individualized Versus Fixed Positive End- Expiratory Pressure (PEEP) in patients Undergoing Laparoscopic Surgery "

Public title
"Individualized Versus Fixed Positive End- Expiratory Pressure (PEEP) in patients Undergoing Laparoscopic Surgery "

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged 20–65 years. ASA physical status I–III. Scheduled for elective laparoscopic Surgery. Willingness to participate and provide informed consent

Exclusion criteria:
• Patients with progressive neuromuscular disease. • Known difficult airway. • Pregnancy. • BMI >35 kg/m^2 • Severe COPD • Severe cardiac disease • Emergency surgeries.

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible patients fulfilling the inclusion criteria will be recruited consecutively until the required sample size is achieved. After obtaining informed consent, participants will be randomly allocated to either the Fixed PEEP group (5 cmH_2O) or the Individualized PEEP group using a computer-generated randomization sequence. Allocation concealment will be maintained using sealed opaque envelopes.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Two-arm parallel-group randomized controlled clinical trail comparing individualized versus fixed positive end expiratory pressure (PEEP) in patient undergoing laparoscopic surgery .

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Superior university lahore

Street address
17km raiwand road,kot araian lahore

City
lahore

Postal code
55150

Approval date
2026-08-24, 1405/06/02

Ethics committee reference number
ref:IRB/FAHS/REHAB/04/26/MS/RS-4100

Health conditions studied

1

Description of health condition studied
Methodology: Randomized Controlled Trial (RCT) will be conducted over four months in the operation theatres of the Department of Anesthesiology at Ayub Teaching Hospital Abbottabad. Patients aged 20 to 65 years, classified as American Society of Anaesthesiology.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
To compare the effect of individualized PEEP versus fixed PEEP on intraoperative

Timepoint
Before intervention (baseline) and intraoperatively after application of the PEEP intervention, at 30 minutes, 60 minutes, and at the end of surgery.

Method of measurement
"PaO_2/FiO_2 ratio will be measured using arterial blood gas (ABG) analysis, with PaO_2 obtained from the ABG analyzer and divided by the corresponding FiO_2."

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayub Teaching Hospital Abbottabad.
Full name of responsible person
Uzair Mustajab
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Main Mansehra Road in Mandian, Abbottabad, Khyber Pakhtunkhwa, Pakistan
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Sponsors / Funding sources

1

Sponsor

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No
Title of funding source
The Superior University Lahore,
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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Superior university lahore
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Dr Usra Naeem
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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
Individualized Versus Fixed Positive End-Expiratory Pressure (PEEP) in Patients Undergoing Laparoscopic Surgery – Study Data De-identified individual participant data (IPD) collected during the study will be shared. The dataset will include demographic and clinical characteristics, intraoperative ventilation parameters (including PEEP, tidal volume, FiO_2, peak airway pressure, lung compliance, plateau pressure, and driving pressure), arterial blood gas measurements including PaO_2/FiO_2 ratio and $PaCO_2$, and postoperative outcomes including oxygen saturation, atelectasis, and pulmonary complications. No directly identifiable participant information will be included.
When the data will become available and for how long
The de-identified individual participant data and related study documents will become available after completion of the study and publication or public availability of the study's summary results. The data will remain available for a period of 5 years following publication of the primary study results. Access will be subject to applicable ethical, confidentiality, and institutional requirements.
To whom data/document is available
Deidentified individual participant data (IPD) and relevant supporting study documents will be shared with qualified researchers and investigators for legitimate scientific and academic research purposes. Requests may be considered from researchers affiliated with academic institutions, healthcare institutions, research organizations, and other organizations, including businesses, provided that the proposed use is scientifically and ethically appropriate. Data will only be shared in a deidentified form and in accordance with applicable ethical, confidentiality, and institutional requirements.
Under which criteria data/document could be used
Deidentified individual participant data (IPD) and supporting study documents will be made available upon reasonable request for legitimate scientific and academic research purposes, including secondary analyses related to perioperative ventilation, individualized PEEP, oxygenation, respiratory mechanics, and postoperative pulmonary outcomes. Requests will be reviewed by the study investigator and, where required, the relevant institutional/ethical authority to ensure that the proposed use is scientifically appropriate and complies with ethical and confidentiality requirements. Data will be provided only in deidentified form. Access will be subject to applicable institutional policies and data-sharing requirements.
From where data/document is obtainable
Applicants wishing to request access to the deidentified individual participant data (IPD) or supporting study documents should contact the study investigator through the research/academic office of The Superior University Lahore. Requests should preferably be submitted by email and should include the applicant's name, institutional affiliation, contact information, purpose of the proposed data use, and a brief description of the intended analysis. Contact person: Uzair Mustajab, Student Investigator Supervisor: Dr. Usra Naeem Institution: The Superior University Lahore, Faculty of Allied Health Sciences Email: uzairjahangere675@gmail.com Telephone:+923135156669
What processes are involved for a request to access data/document
Applicants should submit a request by email, including their affiliation, purpose of data use, and intended analysis. Requests will be reviewed for ethical and confidentiality requirements. Approved deidentified data will be shared securely within approximately 3–6 weeks of receiving a complete request
Comments
All shared data will be deidentified and provided in accordance with applicable ethical, confidentiality, and institutional requirements. The study investigator reserves the right to decline requests that do not meet these requirements.