ISRCTN91065944 https://doi.org/10.1186/ISRCTN91065944

Optimizing respiratory function in obese laparoscopic bariatric surgery: the role of positive end-expiratory pressure

Submission date
21/11/2023

Recruitment status
Recruiting

Registration date
28/11/2023

Overall study status
Ongoing

Last Edited
24/11/2023

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to understand how three different settings of positive end-expiratory pressure (PEEP) affect the breathing and oxygen levels in morbidly obese patients having laparoscopic bariatric surgery. This surgery is a minimally invasive way to change the stomach and intestines to treat obesity and related issues. PEEP is like a setting on a ventilator that helps keep the lungs open while the patient is under general anesthesia and mechanically ventilated.

Who can participate?
Adult patients aged between 18 and 65 years old with morbid obesity who are scheduled for laparoscopic sleeve gastrectomy surgery

What does the study involve?
In this study, participants will be placed into one of three groups:

1. Fixed PEEP: This group will have a constant PEEP level of 10 cmH2O maintained throughout the surgery.
2. Fixed Best PEEP: The best PEEP level for each individual will be determined before the surgery through a trial, and this optimal level will be maintained throughout the entire anesthesia.
3. Variable Best PEEP: The best PEEP level for each phase of the surgery (before, during, and after pneumoperitoneum) will be determined through separate trials for each phase.
The study will assess blood gas levels and respiratory mechanics in different stages of the surgical procedure (before, during, and after pneumoperitoneum).

What are the possible benefits and risks of participating?
The potential benefits of participating in this study include improved gas exchange and respiratory mechanics as the use of individualized PEEP settings may improve respiratory mechanics and gas exchange in obese patients undergoing laparoscopic bariatric surgery. Improved respiratory mechanics and gas exchange may also reduce the risk of postoperative pulmonary complications.

The potential risks of participating in this study include complications related to anesthesia and surgery. These complications can occur in any surgery, regardless of the PEEP setting used. There may also be risks associated with PEEP. These complications are rare, but they can include lung injury and barotrauma (air leaks in the lungs or chest).

The alternative to participating in this study is to receive standard PEEP management during laparoscopic bariatric surgery. Standard PEEP management typically involves using a fixed PEEP ≥10 cmH2O.

Where is the study run from?
University Medical Hospital of Padova (Italy)

When is the study starting and how long is it expected to run for?
December 2022 to December 2025

Who is funding the study?
University Medical Hospital of Padova (Italy)

Who is the main contact?
Prof Michele Carron, michele.carron@unipd.it (Italy)

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Role of positive end-expiratory pressure on respiratory mechanics and gas exchange in obese patients undergoing laparoscopic bariatric surgery

Acronym
PEEPOBESITY

Study objectives
To verify whether there is a possible respiratory benefit in customizing the PEEP setting at each phase of laparoscopic surgery (presence or absence of pneumoperitoneum) compared to a fixed setting or a single evaluation at the beginning of surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/07/2023, Veneto Central-East Area Ethics Committee (CET-ACEV) (Via Giustiniani, 1, Padova, 35128, Italy; +390498212341; ce.sperimentazione@aopd.veneto.it), ref: 5807/AO/23

Study design
Single-centre interventional double-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, University/medical school/dental school

Study type(s)
Efficacy

Participant information sheet
Not available in web format, please use contact details to request a partecipant information sheet

Health condition(s) or problem(s) studied
Morbid obesity

Interventions

Adult patients with morbid obesity (BMI ≥ 40 kg/m2 or BMI ≥ 35 kg/m2 with comorbidities) scheduled for laparoscopic sleeve gastrectomy will be considered for the study. Patients will be classified as ASA III according to the American Society of Anesthesiologists (ASA) physical status classification system.

The intervention in this study involves setting the mode of positive end-expiratory pressure (PEEP) during mechanical ventilation for obese patients undergoing laparoscopic bariatric surgery. An anesthesiologist will determine the PEEP according to the patient's randomized group. A designated investigator will record data on a specific data collection form. An anesthesiologist, not involved in intraoperative care and blinded to the randomized group assignment, will monitor postoperative care in line with the study's endpoints and enter postoperative data into the data collection form. The patient will be blinded to their randomized group assignment.

Randomization is performed by an investigator not involved in the anesthetic management using a sealed envelope system (allocation concealment) with an online generator (https://www.sealedenvelope.com). The patient is not aware of the assigned study group. The anesthesiologist responsible for the intervention becomes aware of the assignment group at the induction of general anesthesia before establishing mechanical ventilation. Postoperative assessment is performed by an investigator unaware of the patient's assignment to the study group.

Eligible participants will be randomly assigned to one of three groups:
1. Fixed PEEP: a fixed PEEP of 10 cmH2O will be maintained throughout the surgical procedure.
2. Fixed Best PEEP: the optimal PEEP level will be determined using a decremental PEEP trial before pneumoperitoneum and maintained at that level for the duration of anesthesia.
3. Variable Best PEEP: the optimal PEEP level will be determined using a decremental PEEP trial for each phase of the surgical procedure (pre-, during, and post-pneumoperitoneum).

Based on the study protocol, the study duration and follow-up extend until the patient's discharge from the hospital. This implies that the study involves monitoring the patient's condition and collecting data throughout their hospitalization following the surgical procedure. This approach allows for a comprehensive assessment of the intervention's effects on both intraoperative and postoperative outcomes. Once discharged, the patient may refer to the surgeons of the department that discharged them for any issues arising after discharge that require evaluation or readmission to the hospital

Anesthesiologists, surgeons, and nurses involved in the study routinely manage these patients.

Anesthesiologist
Expertise:
1. Board-certified anesthesiologist with extensive experience in managing the anesthetic care of morbidly obese patients undergoing laparoscopic bariatric surgery.
2. Possesses in-depth knowledge of respiratory physiology and pharmacology, particularly in the context of mechanical ventilation and PEEP management.
3. Demonstrates expertise in airway management, hemodynamic monitoring, and critical care interventions.
Background:
1. Completed an accredited residency program in anesthesiology.
2. Participated in continuing medical education (CME. courses to stay up-to-date with the latest

advancements in anesthesiologic care.
3. Actively involved in research and publications related to anesthetic management of bariatric surgery patients.

Surgeon
Expertise:
1. Board-certified surgeon with extensive experience in performing laparoscopic bariatric surgery, including laparoscopic sleeve gastrectomy
2. Possesses in-depth knowledge of the surgical techniques and potential complications associated with bariatric surgery.
3. Demonstrates expertise in patient selection, preoperative evaluation, and postoperative care.
Background:
1. Completed an accredited residency program in general surgery.
2. Participated in advanced laparoscopic surgery training programs.
3. Actively involved in research and publications related to bariatric surgery techniques and outcomes.

Nurse
Expertise:
1. Registered nurse (RN. with extensive experience in caring for morbidly obese patients undergoing laparoscopic bariatric surgery.
2. Possesses in-depth knowledge of the physiological changes and potential complications associated with bariatric surgery.
3. Demonstrates expertise in patient education, medication administration, and postoperative monitoring.
Background:
1. Completed an accredited nursing program and obtained RN licensure.
2. Participated in continuing nursing education (CNE. courses to stay up-to-date with the latest advancements in bariatric nursing care.
3. Actively involved in patient advocacy and promoting patient-centered care.

Anesthesiologists, surgeons, and nurses received thorough training on the study protocol and participated in discussions with the team to ensure optimal coordination and communication during the perioperative care.

The intervention is delivered individually to each patient, and the mode of delivery is face-to-face. The face-to-face interaction between the anesthesiologist and the patient allows for personalized care and ensures that the intervention is delivered safely and effectively. The study took place in multiple settings. During the early perioperative phase, it was conducted in the operating room and the recovery room, where essential medical equipment and monitoring systems are available to ensure patient safety and effective management. Following the surgery, it continued in the ward, where patients were transferred for ongoing care. This setting provided a controlled environment for recovery, with necessary medical support and monitoring infrastructure.

Intervention Type
Procedure/Surgery

Primary outcome measure
The effect of different positive end-expiratory pressure (PEEP) setting regimens on intra-operative oxygenation measured using the PaO2/FiO2 ratio of arterial oxygen partial pressure

[PaO2 in mmHg] to fractional inspired oxygen [FiO2 expressed as a fraction, not a percentage]. Parameters are monitored in a standard manner for general anesthesia.

Secondary outcome measures
The following secondary respiratory and cardiovascular variables are measured during the intraoperative time points: pre-peritoneum, during pneumoperitoneum, and after pneumoperitoneum. Parameters are monitored in a standard manner for general anesthesia:
1. Respiratory variables: Peak Inspiratory Pressure (cmH2O), Plateau Pressure (cmH2O), Positive End-Expiratory Pressure (PEEP) (cmH2O), Elastance (cmH2O/l), Compliance (ml/cmH2O), Inspiratory Flow (L/min), Respiratory Rate (breaths/min), Driving Pressure (cmH2O), Mechanical Power, Arterial Oxygen Saturation measured by Pulse Oximetry (SpO2) (%), Arterial Partial Pressure of Oxygen (PaO2) (mmHg), Arterial Partial Pressure of Carbon Dioxide (PaCO2) (mmHg), Arterial pH
2. Cardiovascular variables: Systolic Blood Pressure (mmHg), Diastolic Blood Pressure (mmHg), Heart Rate (bpm)

The following secondary post-anesthesia phase and ward discharge variables are measured at the following postoperative time points: 0, 15, 30, 60, 90, and 120 minutes after tracheal extubation, and 6, 24, 48, and 72 hours after surgery:
1. Pain intensity measured using a Numeric Rating Scale (NRS 0-10)
2. Intensity of nausea and/or vomiting measured using the NRS 0-10
3. Postoperative pulmonary complications (POPCs)

Overall study start date
01/12/2022

Completion date
01/12/2025

Eligibility

Key inclusion criteria
1. Aged 18 years old and over
2. Morbid obesity (BMI ≥ 40 kg/m2 or BMI ≥ 35 kg/m2 with comorbidities)
3. Laparoscopic sleeve gastrectomy surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
45

Key exclusion criteria
1. Severe acute and/or chronic respiratory disease (e.g., asthma, COPD, severe restrictive disease)
2. Severe acute and/or chronic heart disease (e.g., acute or recent myocardial infarction, inducible ischemia, heart failure)
3. End-stage liver and kidney disease
4. Intolerance or allergy or contraindications to the drugs used

Date of first enrolment
01/12/2023

Date of final enrolment
01/10/2025

Locations

Countries of recruitment
Italy

Study participating centre
University Medical Hospital of Padua
Via Giustiniani, 2
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35128

Sponsor information

Organisation
University Medical Hospital of Padova

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
https://www.aopd.veneto.it/Progetti-e-Ricerca-Clinica

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Hospital of Padova

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/12/2026

Individual participant data (IPD) sharing plan
The dataset generated during and/or analysed in the current study will be available from the corresponding author, Prof Michele Carron, michele.carron@unipd.it, on reasonable request.

Data collected for study purposes are available upon reasonable request and will be provided within a timeframe compatible with the nature of the inquiry. Consent from participants is both required and obtained. The study strictly adheres to data anonymization protocols to ensure the confidentiality and privacy of participant information. All identifiable personal details are removed or altered in the dataset to prevent the possibility of tracing back to individual participants. This process is crucial for maintaining the integrity of the study and upholding ethical standards in research. This study is conducted in compliance with all relevant ethical guidelines and legal regulations. It has received approval from the appropriate ethics review boards. We ensure adherence to the principles of the Declaration of Helsinki and local laws governing clinical research. The study involves human subjects and, therefore, strict confidentiality and informed consent protocols are followed. There are legal restrictions to protect patient confidentiality and privacy.

IPD sharing plan summary
Available on request