PRotective Ventilation with Higher versus Lower PEEP during General Anesthesia for Surgery in OBESE Patients - The PROBESE Randomized Controlled Trial

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To compare a ventilation strategy using higher levels of PEEP with recruitment maneuvers with one using lower levels of PEEP without recruitment maneuvers in obese patients at an intermediate-to-high risk for PPCs.We hypothesize that an intra-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON44595

Source
ToetsingOnline

Brief title
PROBESE

Condition

- Respiratory disorders NEC

Synonym
Ventilator associated lung injury

Research involving
Human

Sponsors and support

Primary sponsor: Technische Universität Dresden
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: mechanical ventilation, obesity, PEEP, pulmonary complications

Outcome measures

Primary outcome

Postoperative pulmonary complications:

Aspiration pneumonitis

Bronchospasm

Mild respiratory failure

Moderate respiratory failure

Severe respiratory failure

ARDS

Pulmonary infection

Atelectasis

Cardiopulmonary edema

Pleural effusion

Pneumothorax

New pulmonary infiltrates

Secondary outcome

Secondary endpoints include intra-operative complications, need for

postoperative ventilatory support (invasive and/or non-invasive ventilation),

need for unexpected ICU admission or ICU readmission, the number of hospital-

free days and 90-day survival/mortality.

Study description

Background summary

Postoperative respiratory failure, particularly after surgery under general anesthesia, adds to the morbidity and mortality of surgical patients. Anesthesiologists inconsistently use positive end-expiratory pressure (PEEP) and recruitment maneuvers in the hope that this may improve oxygenation and protect against postoperative pulmonary complications (PPCs), especially in obese patients. While it is uncertain whether a strategy that uses higher levels of PEEP with recruitment maneuvers truly prevents PPCs in these patients, use of higher levels of PEEP with recruitment maneuvers could compromise intra-operative hemodynamics.

Study objective

To compare a ventilation strategy using higher levels of PEEP with recruitment maneuvers with one using lower levels of PEEP without recruitment maneuvers in obese patients at an intermediate-to-high risk for PPCs.
We hypothesize that an intra-operative ventilation strategy using higher levels of PEEP and recruitment maneuvers, as compared to ventilation with lower levels of PEEP without recruitment maneuvers, prevents PPCs in obese patients at an intermediate-to-high risk for PPC.

Study design

International multicenter randomized controlled trial.

Intervention

Patients with be either ventilated with PEEP of 12 cmH2O with the use of recruitment maneuvers (the *higher PEEP level*), or PEEP of 4 cmH2O without recruitment maneuvers (the *lower PEEP level*). The higher PEEP level group can be seen as the intervention group.

Study burden and risks

In the intra-operative period, patients will not experience discomfort from either strategy because of general anesthesia. However, systemic hypotension could occur in the higher PEEP group, which would be treated with intravascular volume therapy and/or vasoactive drugs. If the hypothesis proves to be true,

patients in the higher PEEP group could benefit from a lower incidence of PPCs.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Patient scheduled for surgery under general anesthesia
• Intermediate-to-high risk for postoperative pulmonary complications following surgery, according to the ARISCAT risk score (>= 26)
• BMI >= 35 kg/m2
• Expected duration of surgery >= 2 h

Exclusion criteria

• Age < 18 years
• Previous lung surgery (any)
• Persistent hemodynamic instability, intractable shock (considered hemodynamically unsuitable for the study by the patient*s managing physician)
• History of previous severe chronic obstructive pulmonary disease (COPD) (non-invasive ventilation and/or oxygen therapy at home, repeated systemic corticosteroid therapy for acute exacerbations of COPD)
• Recent immunosuppressive medication (patients receiving chemotherapy or radiation therapy up to two months prior to surgery)
• Severe cardiac disease (New York Heart Association class III or IV, acute coronary syndrome or persistent ventricular tachyarrhythmias)
• Invasive mechanical ventilation longer than 30 minutes (e.g., general anesthesia for surgery) within last 30 days
• Pregnancy (excluded by anamneses and/or laboratory analysis)
• Prevalent acute respiratory distress syndrome expected to require prolonged postoperative mechanical ventilation
• Severe pulmonary arterial hypertension, defined as systolic pulmonary artery pressure > 40 mmHg
• Intracranial injury or tumor
• Neuromuscular disease (any)
• Need for intraoperative prone or lateral decubitus position
• Need for one-lung ventilation
• Cardiac surgery
• Neurosurgery
• Planned reintubation following surgery
• Enrolled in other interventional study or refusal of informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	04-11-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02148692
CCMO	NL50188.018.14