

# 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-...

|                              |                           |
|------------------------------|---------------------------|
| <b>Ethical review</b>        | Approved WMO              |
| <b>Status</b>                | Recruitment stopped       |
| <b>Health condition type</b> | Respiratory disorders NEC |
| <b>Study type</b>            | 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 will be either ventilated with PEEP of 12 cmH<sub>2</sub>O with the use of recruitment maneuvers (the \*higher PEEP level\*), or PEEP of 4 cmH<sub>2</sub>O 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

### Public

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### Scientific

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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 ( $\geq 26$ )
- BMI  $\geq 35$  kg/m<sup>2</sup>
- Expected duration of surgery  $\geq 2$  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 |