

## Why is this study needed?

### Medical problem

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 using higher levels of PEEP with recruitment maneuvers truly prevents PPCs in these patients, the use of higher levels of PEEP with recruitment maneuvers could compromise intra-operative hemodynamics.

### Hypothesis

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.

### ClinicalTrials.gov Identifier

NCT 021 486 92

# JOIN THE PROBESE TRIAL

### Steering Committee

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for the PROBESE Investigators

### Contact

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### Further information

[www.peg-dresden.de/probese](http://www.peg-dresden.de/probese)  
[www.provenet.eu](http://www.provenet.eu)  
[www.esahq.org/research](http://www.esahq.org/research)



Protective  
Ventilation with  
Higher versus Lower  
PEEP during General  
Anesthesia for  
Surgery in Obese  
Patients



### Study design

International multicenter double-blinded randomized controlled trial of 748 patients

### Main study parameters/endpoints

The primary endpoint is the proportion of patients with PPCs. Secondary endpoints include intra-operative complications, need for postoperative ventilatory support (invasive and/or non-invasive ventilation), unexpected ICU admission or ICU readmission, the number of hospital-free days on postoperative day 90 and 90-day survival/mortality.

### Intervention

#### **THE HIGHER PEEP LEVEL**

Mechanical ventilation with protective tidal volume of 7ml/kg PBW and the level of PEEP at 12 cmH<sub>2</sub>O with lung recruitment maneuvers performed hourly

**vs.**

#### **THE LOWER PEEP LEVEL**

Mechanical ventilation with protective tidal volume of 7ml/kg PBW and the level of PEEP at 4 cmH<sub>2</sub>O without lung recruitment maneuvers

### Follow up

There will be daily visits on postoperative days 1, 2, 3, 4, 5 and at discharge from hospital, as well as telephone contact at day 90.

### Inclusion criteria

Obese adult patients with body mass index (BMI)  $\geq 35$  kg/m<sup>2</sup> at intermediate-to-high risk for PPCs<sup>1</sup> scheduled for open or laparoscopic surgery under general anesthesia lasting for at least 2 h.

### Key exclusion criteria

- Previous lung surgery
- Persistent hemodynamic instability or intractable shock
- History of severe chronic obstructive pulmonary disease (COPD)
- Recent immunosuppressive medication
- Severe cardiac disease
- Invasive mechanical ventilation longer than 30 minutes within last 30 days
- Prevalent acute respiratory distress syndrome expected to require prolonged postoperative mechanical ventilation
- Severe pulmonary arterial hypertension
- Intracranial injury or tumor
- Neuromuscular disease
- Need for intraoperative prone or lateral decubitus position
- Need for one-lung ventilation
- Cardiac or Neurosurgery
- Planned reintubation following surgery

<sup>1</sup> Canet, J., Anesthesiology, 2010;113(6)

### Become a co-author !

You are eligible for a co-authorship for every 12 randomized patients successfully treated according to the study protocol. Furthermore, you are allowed to run your own substudy upon application to the PROBESE steering committee.

### Clinical implication

The result of this important clinical investigation may change our daily clinical practice in anesthesia of obese patients. Considering the growing burden of obesity and morbid obesity in the operating rooms all around the world, this trial might impact on post-operative outcomes and length of hospital stay in a great way.

### How do you get involved?

We plan to recruit study centers worldwide caring for patients with severe to morbid obesity who undergo general anesthesia for an at least 2-hour surgical intervention. If your daily anesthetic routine includes such patients and you want to be part of our team, please contact Thomas Bluth (study coordinator) at [probese@peg-dresden.de](mailto:probese@peg-dresden.de).