**Why is this study needed?**

**Medical problem**
One-lung ventilation (OLV) with resting of the contralateral lung may be required to allow or facilitate thoracic surgery. However, OLV can result in severe hypoxemia, requiring a mechanical ventilation approach that is able to maintain adequate gas exchange, while protecting the lungs against postoperative pulmonary complications (PPCs). During OLV, the use of lower tidal volumes is helpful to avoid over-distension, but can result in increased atelectasis and repetitive collapse-and-reopening of lung units, particularly at low levels of positive end-expiratory pressure (PEEP).

Anesthesiologists inconsistently use PEEP and recruitment maneuvers (RM) in the hope that this may improve oxygenation and protect against PPC. Up to now, it is not known whether high levels of PEEP combined with RM are superior to lower PEEP without RM for protection against PPCs during OLV.

**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 postoperative pulmonary complications in patients undergoing thoracic surgery under standardized one-lung ventilation.

**Join the largest study on mechanical ventilation during thoracic surgery ever!**

**Actively participating centers**
- University Hospital Istanbul, Turkey
- University Hospital Dresden, Germany
- University Hospital Magdeburg, Germany
- Coswig Hospital, Germany
- University Hospital Münster, Germany
- NYC Cornell Medical College, USA
- University Hospital Munich, Germany
- Hospital General Universitario de Valencia, Spain
- University Hospital Freiburg, Germany
- Insular Hospital, Gran Canaria, Spain
- Academic Medical Center Amsterdam, NL
- University Hospital Aachen, Germany
- Hospital Álvaro Cunqueiro, Vigo, Spain
- University Hospital Centre Zagreb, Croatia
- “Sotiria” Chest Hospital, Athens, Greece
- Institutul de Pneumoftiziologie Bucarest, RO
- Military Medical Academy, Belgrade, Serbia
- Hospital Universitario de La Ribera, Spain
- Ospedale Policlinico San Martino, Genova, Italy
- University Hospital, Prague, Czech Republic
- University Hospital Clinic de Barcelona, Spain
- Central Military University Hospital Bucharest
- Radboud University Medical Centre Nijmegen, NL
- Attikon University Hospital, Athens, Greece
- University Medical Centre Ljubljana, Slovenia
- OORR Foggia, University of Foggia, Italy
- ......your center ?

**PROtective ventilation with high versus low PEEP during one-lung ventilation for THORacic surgery**

**Principal Investigator**
Mert Sentürk, Turkey

**Contact**
Please contact Thomas Kiss (study coordinator) by e-mail at prothor@peg-dresden.de or at the ESA Secretariat (research@esahq.org)
How is this study designed?

Study design
International multicenter double-blinded randomized controlled trial of 2378 patients

Study endpoints
The primary endpoint is the proportion of patients with postoperative pulmonary complications (PPC). Secondary endpoints include intra-operative complications, postoperative extra-pulmonary complications, extended PPC, need for unexpected intensive care unit (ICU) admission or ICU readmission, number of hospital-free days at day 28, 90-day survival, arterial blood gas analysis during surgery, need for postoperative respiratory interventions (e.g. non-invasive ventilation (NIV) or continuous positive pressure (CPAP) or intubation or high flow nasal cannula).

Which patients are studied?

Inclusion criteria
- Non-obese (BMI < 35 kg/m²) adult patients scheduled for open thoracic or video-assisted thoracoscopic surgery under general anesthesia requiring one-lung ventilation with double lumen tube use for lung separation
- expected duration of surgery > 60 min
- most of ventilation time during surgery expected to be in one-lung ventilation

Key exclusion criteria
- esophagectomy, pleural surgery only, sympathectomy only, chest wall surgery only, mediastinal surgery only, lung transplantation
- documented preoperative hypercapnia > 45 mmHg (6 kPa)
- documented pulmonary arterial hypertension at rest: > 25 mmHg MPAP or > 40 mmHg syst.
- previous lung surgery
- planned mechanical ventilation after surgery
- bilateral procedures
- lung separation with other method than double lumen tube (e.g. difficult airway, tracheostomy)
- surgery in prone position
- COPD GOLD grades III and IV, lung fibrosis, documented bullae, severe emphysema, pneumothorax
- Heart failure NYHA Grade 3 and 4, Coronary Heart Disease CCS Grade 3 and 4
- documented or suspected neuromuscular disease

Why should you participate?

Become a co-author!
You are eligible for a co-authorship for every 20 randomized patients successfully treated according to the study protocol. Furthermore, you are allowed to run your own substudy upon application to the steering committee.

Clinical implication
The result of this important clinical investigation may change our daily clinical practice in anesthesia of patients for thoracic surgery. This trial might impact on postoperative 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 who undergo one-lung ventilation for thoracic surgery. If your daily anesthetic practice includes such patients and you want be to part of our team, please contact Thomas Kiss at prothor@peg-dresden.de

Intervention
THE HIGHER PEEP LEVEL
Mechanical ventilation with VT of 5 ml/kg PBW and the level of PEEP at 10 cmH₂O with lung recruitment maneuvers

THE LOWER PEEP LEVEL
Mechanical ventilation with VT of 5 ml/kg PBW and the level of PEEP at 5 cmH₂O 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.