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 PROTHOR TRIAL !

Steering Committee (alphabetical)

J. Canet, Spain ♦ M. El Tahan, Saudi Arabia ♦ C. Ferrando Ortola, Spain ♦ C. Gregoretti, Italy ♦ M. Granell, Spain ♦ M. Gama de Abreu, Germany ♦ T. Hachenberg, Germany ♦ W. Karzai, Germany ♦ T. Kiss, Germany ♦ T. Loop, Germany ♦ M-J, Licker, Switzerland ♦ G H. Mills, United Kingdom ♦ Z. Nisnevitch-Savarese, USA ♦ P. Pelosi, Italy ♦ G. della Rocca, Italy ♦ R. Rossaint, Germany ♦ M. Schultz, The Netherlands ♦ M. Sentürk, Turkey ♦ P. Severgnini, Italy ♦ E. O'Sullivan, Ireland ♦ L. Szegedi, Belgium ♦ C. Unzueta, Spain ♦ T. Vegh, Hungary, for the PROTHOR Investigators

Contact

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

Further information

www.peg-dresden.de/prothor
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European Society of Anaesthesiology ESA

Endorsed by ESA

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

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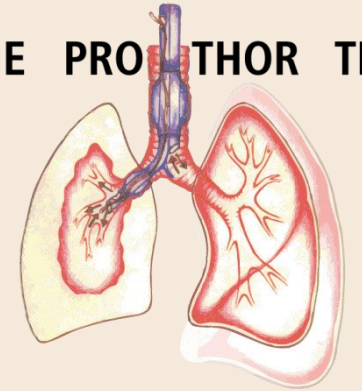
THE PROTHOR TRIAL



Principal Investigator

Mert Sentürk, Turkey

Study coordinator

Thomas Kiss, Germany

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).

Intervention

THE HIGHER PEEP LEVEL

Mechanical ventilation with VT of 5 ml/kg PBW and the level of PEEP at 10 cmH_2O with lung recruitment maneuvers

THE LOWER PEEP LEVEL

Mechanical ventilation with VT of 5 ml/kg PBW and the level of PEEP at 5 cmH_2O 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.

Which patients are studied ?

Inclusion criteria

- Non-obese (BMI < 35 kg/m^2) 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 12 randomized patients** successfully treated according to the study protocol. Furthermore, you are allowed to run your own substudy upon application to the PROTHOR steering committee.

Clinical implication

The result of this important clinical investigation may change our daily clinicial practice in anesthesia of patients for thoracic surgery. 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 who undergo one-lung ventilation for thoracic surgery. If your daily anesthetic practice includes such patients and you want be to be part of our team, please contact Thomas Kiss at

prothor@peg-dresden.de