



Newsletter 7

Dresden, January 31, 2016

Dear National Coordinators and Local Principal Investigators of PROBESE,
Dear friends,

The PROBESE study has just achieved the amazing mark of 734 randomized patients. Congratulations for this achievement, which is a result of **your** invaluable support!

As you certainly remember, our initial goal was to randomize 748 patients. However, the incidence of postoperative pulmonary complications (PPCs) in our population is lower than we estimated, which affects the power of the study. Therefore, and given the high patient inclusion rate, the Data and Safety Monitoring Board (DSMB) recommended us to extend our trial in order to deliver a likely definitive answer to our primary question, namely whether intraoperative mechanical ventilation with high PEEP and recruitment maneuvers reduces the incidence of PPCs compared to low PEEP without recruitment maneuvers.

Following the recommendation of the DSMB, the sample size was re-estimated by a biostatistician with major experience in the design of clinical studies. According to this re-estimation, which now also includes two interim analyses, our study will be continued until 2013 patients have been randomized; making PROBESE the largest randomized controlled trial on intraoperative mechanical ventilation ever. We emphasize that **the policy of collaborative authorship will not be changed**, i.e. a collaborative co-authorship will be granted for every 12 randomized patients. Thus, there will be no disadvantages for centers.

We would very much appreciate if you continue to include patients, but **please consult first with your local regulatory entity** and let us know about this step. Possibly, the attached approval from the Internal Review Board at the PROBESE coordinating center, University Hospital Dresden, Germany, will be useful for your own review board. This document can also be downloaded from the PROBESE homepage at <http://peg-dresden.de/probese/doku.php?id=200:Files>.

Please do not hesitate to contact us if you need further information.

Yours sincerely,



Thomas Bluth, MD
Trial Coordinator
Department of Anesthesiology
and Intensive Care Medicine
University Hospital Dresden
Technische Universität Dresden
Dresden, Germany

Marcelo Gama de Abreu, MD, PhD
Principle Investigator
Department of Anesthesiology
and Intensive Care Medicine
University Hospital Dresden
Technische Universität Dresden
Dresden, Germany

Ary Serpa Neto, MD, MSc, PhD
Department of Intensive Care
Academic Medical Center
University of Amsterdam
Amsterdam, The Netherlands

Marcus J. Schultz, MD, PhD
Department of Intensive Care
Academic Medical Center
University of Amsterdam
Amsterdam, The Netherlands

Sabrine N. T. Hemmes, MD
Department of Intensive Care
and Anesthesiology
Academic Medical Center
University of Amsterdam
Amsterdam, The Netherlands

Paolo Pelosi, MD
Department of Surgical Sciences
And Integrated Diagnostics
University of Genoa
Genoa, Italy