



Newsletter 10

Dresden, November 30, 2016

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

The total number of patients enrolled and breakdown per center are shown in the figure below. Thanks to your unique contribution, almost 250 patients have been randomized since our last newsletter from July 2016, and we are approaching the last quarter of the calculated sample size. Congratulations!

We kindly remind you to complete the online patient data. The next interim analysis will be held in the very beginning of next year and its success highly depends on completeness of data. Thank you for heeding this.

Sub-studies

Rationales, methods and analysis plans for ongoing and already running sub-studies can now be found at <http://www.peg-dresden.de/probese/doku.php?id=200:Substudies>. We would like to call your attention to the sub-study on preoperative oxygen saturation changes (SpO₂) between supine and beach chair position (so-called **OXYGEN STRESS TEST**) from Prof. Canet, Badalona, Spain, which you might easily join.

What changes?

Preoperative SpO₂ will be recorded in beach chair when breathing room air, as foreseen originally. If SpO₂ ≥ 92%, the patient is put in **SUPINE POSITION** and SpO₂ will be e-assessed after 10 min in room air. For those, who wish to join this sub-study, please ask for permission at your IRB using the respective amendment (PROBESE study protocol v2.6). For data collection, you can use the new version of the paper Case Report Form (v1.3). REDCap is already configured for this small change.

Further Sub-studies:

- The impact of protective ventilation with higher versus lower PEEP during general anesthesia on postoperative lung function as assessed by spirometry in morbidly obese



The PROBESE Randomized Controlled Trial

patients undergoing surgery; *L. de Baerdemaeker, Ghent, Belgium; location: Ghent University Hospital*

- Non-linear respiratory system mechanics during low versus high positive end-expiratory pressure during surgery in obese patients; *R. Huhle, T. Bluth, M. Gama de Abreu; Dresden, Germany; location: University Hospitals Dresden and Genoa*

If you are interested in joining these further sub-studies as well, you are most welcome. All you need to do is to contact us, and we will forward your request to the respective authors.

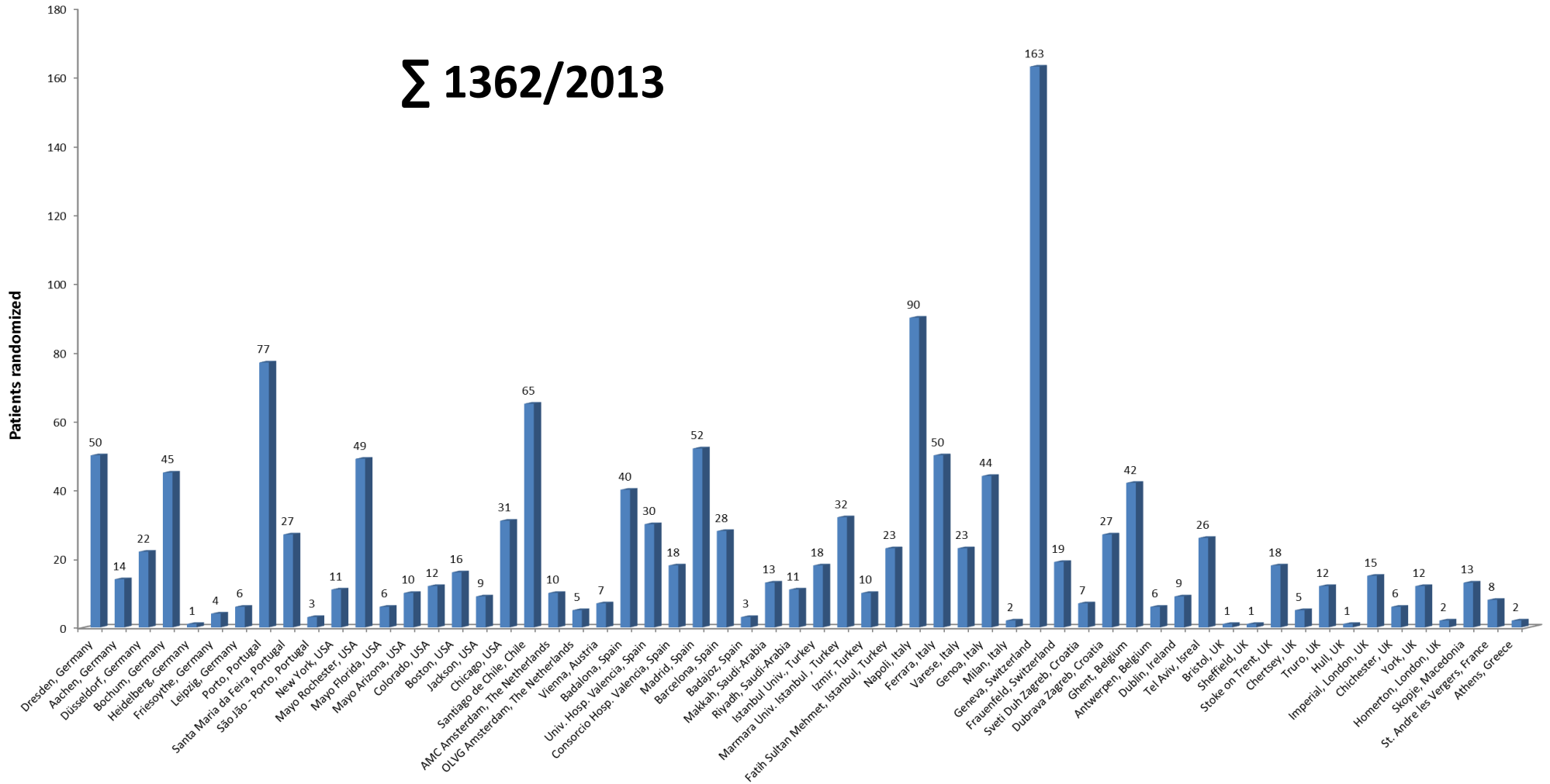
Manuscript of the Study Protocol: The manuscript of the PROBESE study protocol has been submitted to Trials, and we are currently waiting for a decision from the editor.



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

The PROBESE Randomized Controlled Trial

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

Yours sincerely,

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