

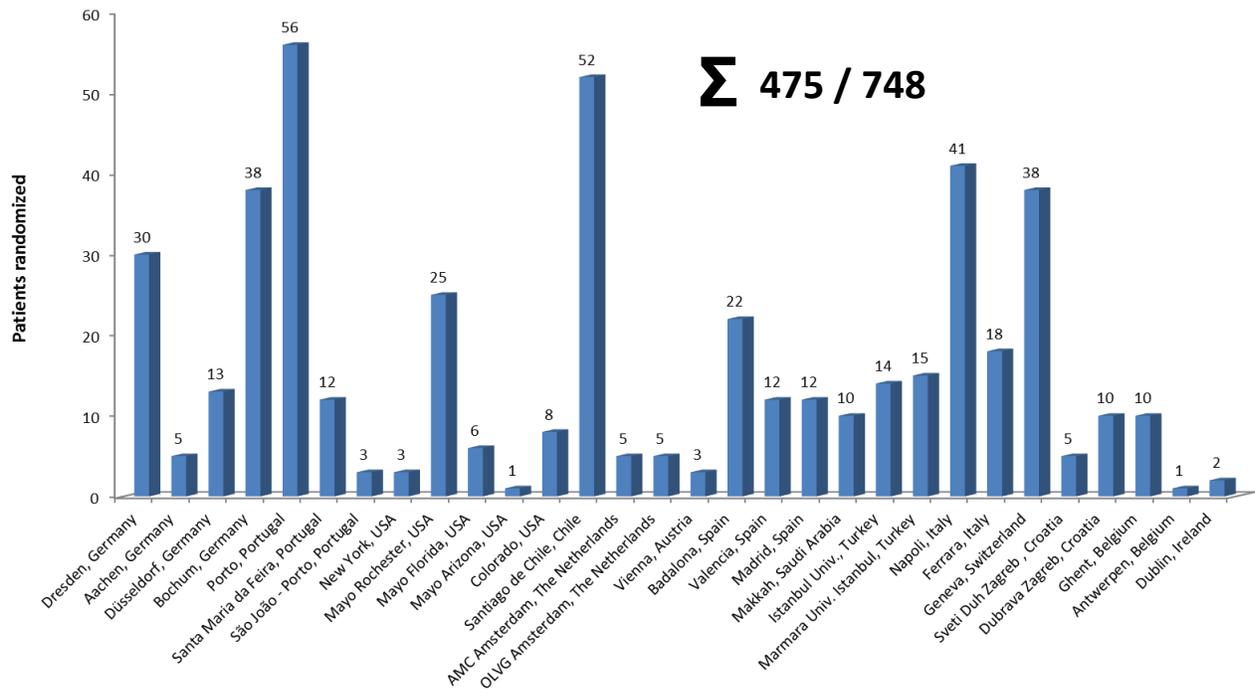


## News Letter 5

Dresden, September 21, 2015

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

Thanks your efforts, 475 out of 748 patients are randomized by today. PROBESE is going on terrifically. Even more important: The Data and Safety Monitoring Board (DSMB) has carefully reviewed the data as well as adverse events, and recommended to continue with the study. The current randomization status per site is shown below:



current status 21/09/2015, 11:00

### Online Monitoring

According to a recommendation of the DSMB we have started with detailed monitoring of the online data. Centers will be contacted and eventually asked to correct or complete their data as needed. In this regard, we emphasize the importance of up-to-date online data. **Please remember that the deadlines for online data entry are:**



- Preoperative visit: two weeks after surgery
- Intraoperative visit: two weeks after surgery
- Postoperative visit (until day 5): three weeks after surgery
- Discharge: two weeks after discharge
- Follow up 90 days: two weeks thereafter

### **Appropriate ventilator settings during recruitment maneuvers**

Since there are still doubts on how to perform the lung recruitment maneuver in PROBESE, we would like to explain this maneuver in detail.

The recruitment maneuver (RM) in PROBESE is achieved by applying comparatively high inspiratory volumes using volume-controlled ventilation with an appropriate inspiratory pressure target. Recruitment might be most effective, if inspiratory volumes/pressures are maintained for a longer period. To achieve this, we recommend to reduce respiratory rate to 6/min and set the I:E ratio at 1:1 (as stated in the protocol). The prolongation of the inspiratory time enables reducing inspiratory flow and the peak airway pressure, whereas the lower respiratory rate reduces the risk of hyperventilation.

During RM please increase first the tidal volume by steps of 4 mL/kg (predicted body weight) until the maximum volume deliverable by the ventilator is reached, and only as long as the target inspiratory plateau pressure (P<sub>plat</sub> of 40 to 50 cmH<sub>2</sub>O) is not achieved. In a second step, PEEP can be increased up to 20 cmH<sub>2</sub>O if the maximum tidal volume has been delivered and P<sub>plat</sub> is still < 40 to 50 cmH<sub>2</sub>O. If both the maximal tidal volume and PEEP values have been achieved, but P<sub>plat</sub> is < 40 to 50 cmH<sub>2</sub>O, 3 respiratory cycles are allowed and the last P<sub>plat</sub> documented: the maneuver can be still considered successful and the ventilatory settings of the protocol resumed. If you have questions, please do not hesitate to contact us.



The PROBESE Randomized Controlled Trial

Yours sincerely,

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