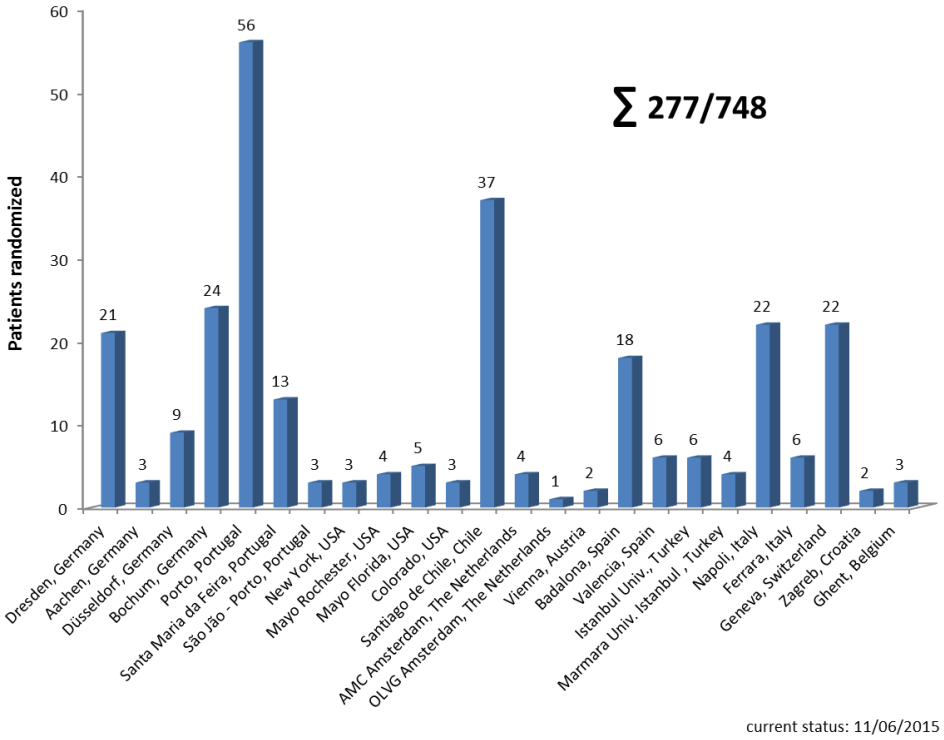
News Letter 4

Dresden, June 13, 2015

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

Euroanaesthesia 2015 just went down in history but the discussions we had during the congress in Berlin showed us once more that the results of PROBESE are highly needed. The Data and Safety Monitoring Board is satisfied about enrolment rate, but there is still much work to do. Therefore, if you do not have IRB approval at this time, please try to get it and start including patients as soon as possible.



In this newsletter, we give you a short summary of issues discussed during the last steering committee meeting in Berlin, and address frequently asked questions.

Screening

During their meeting, the steering committee members recommended introducing a screening log file in order to keep track of the patients that **met all inclusion criteria but were not randomized**.

This could be valuable information for reviewers of the manuscript. If you have already used such a log file since the beginning of the study, we will use the complete data you collected. Furthermore, we would be happy, if you are able to retrieve screening data retrospectively. In any other case, please report the number of patients with reason of randomization failure (e.g. exclusion criteria, organizational issues etc.) from now on. For this, please use the file attached to this email or download it from www.peg-dresden.de/probese/doku.php?id=200:Files.

Follow up on day 90

There were some uncertainties about recording of the parameter *hospital free days on postop day 90*. Please contact the patient by phone and ask explicitly for readmission to hospital after discharge following the first in-hospital stay and postoperative day 90. Hospital free days are then calculated as follows:

90 days – [postop days of initial stay] – [days of further hospital stay until day 90]

Calculation of dosage of volatiles during anesthesia

Please calculate the consumption of volatiles as follows: **C_{et} mean [vol%] * t [min]**, where C_{et} mean refers to mean end-tidal volatile concentration and t refers to time of application.

In case that dosage changes over time please calculate the sum of different concentration/time products as follows : $[C_{et}\ mean_1 * t_1] + [C_{et}\ mean_2 * t_2] + ... + [C_{et}\ mean_n * t_n]$.

Auto-PEEP

As stated in the protocol, auto-PEEP should be ideally avoided. The methods to detect auto-PEEP may differ among centers, and appropriate settings of inspiratory/expiratory ratio should be considered in this regard, even if a protocol deviation results. As far as possible, the tidal volume should be maintained at 7 mL/kg of predicted body weight when dealing with auto-PEEP.

Next meeting of the DSMB

The Data Safety and Monitoring Board will have a video-conference with the chief investigator, the international trial coordinator and members of the ESA Clinical Trial Network after 300 randomized patients to discuss the study progress. We expect to reach this number by end of June. Please complete your eCRF data as much as possible, including detailed reports about (severe) adverse events.

Please let us know if you need any further information or help to run this endeavor.

Yours sincerely,

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