



Newsletter 11

Dresden, January 25, 2017

Dear National Coordinators and Local Principal Investigators of PROBESE,

Dear friends,

We hope you had a good start in 2017. We are extremely happy to see that patient enrollment remains impressively high. Please keep in mind that we need complete data sets in REDCap for the second interim analysis until February, 6. We would like to call your attention to a couple of issues regarding patient discharge from the study.

Early discharge from hospital (before postop day 5)

Please note that once patients have been discharged from hospital, this must be documented in the eCRF (REDCap) during all postoperative days. The option “discharge” appears in the same field as “lost to follow up”. Upon discharge, the data set should be entered twice, i.e. in the respective postoperative day AND the discharge form.

Lost to follow up

Until recently, the possibility to adequately report cases of lost to follow up for other reason (beside death and refused consent) was not given in REDCap. We added a field to enter free text, and kindly ask you to use it as appropriate.

Randomization not followed by adequate study treatment

For different reasons, randomization was not followed by treatment as foreseen in the protocol in a few patients. Therefore, uncertainties about follow up and appropriate documentation in REDCap arose. In the table provided below, you will find a short guide on how to deal with such cases. Should you still have doubts regarding a particular case, please contact the trial coordinator.

Please keep always in mind that patients should be randomized as close as possible to anesthesia induction and intubation.



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

The PROBESE Randomized Controlled Trial

patient entered in REDCap with ID	randomized	special circumstance	intraop treatment according to protocol	follow up day 1 - day 90	action in REDCap
yes	no	all	not to be done	not to be done	no intraop or postop data to be entered (preop data set to be kept in)
yes	yes	surgical procedure cancelled, postponed or changed	not possible	not to be done	intraop visit – randomization form; answer new REDCap question: <i>surgical procedure cancelled, postponed or changed and patient NOT treated = yes</i> ; no postop data to be entered
yes	yes	new exclusion criteria or lack of inclusion criteria after randomization	patient must not receive intervention	not to be done	change exclusion/ inclusion criteria accordingly no other intraop or postop data to be entered
yes	yes	received wrong intervention, or no intervention	no	to be done according to intention-to-treat principle	intraop visit – protocol deviation form; describe protocol deviation in detail postop data to be entered completely



Yours sincerely,

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