

PROTHOR Newsletter 11/2020

Dresden, November 24, 2020

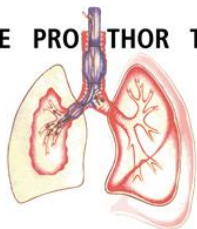
Dear National Coordinators and Local Investigators of PROTHOR,

Most of us are facing a second or even third wave of the Covid-19 pandemic. Nevertheless, patient recruitment in the PROTHOR-trial continues and we aim to maintain it as much and as long as possible. To keep an overview of the trial, kindly inform us about a potential temporary inclusion stop in your center. Furthermore, please inform us if you need any further assistance with the study during the pandemic. If you have the chance to keep on with patient recruitment, this would help PROTHOR to advance.

DSMB meeting and second interim analysis

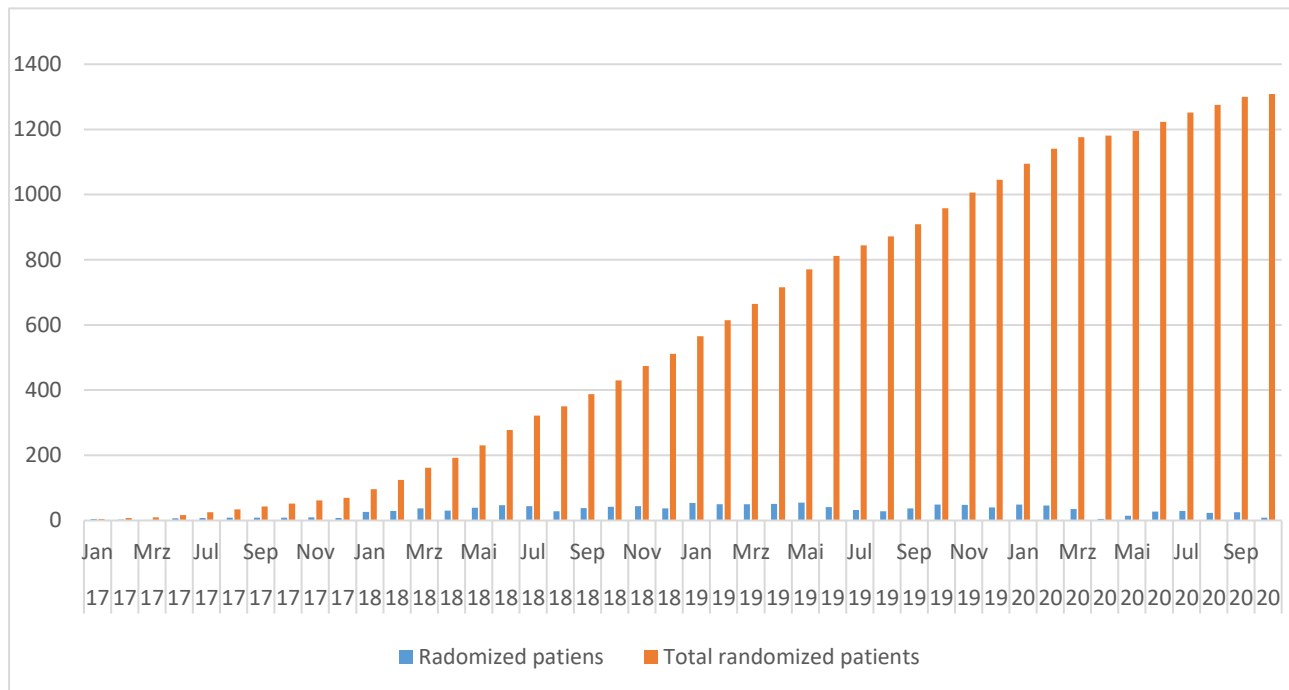
The PROTHOR DSMB met November 16th by video-conference to discuss the results of the second interim analysis. Members present were Daniel Sessler (Chair), Arthur Slutsky, Jean-Louis Vincent, and Jennifer Hunter. Andreas Hoeft apologized for absence. In a closed session, the Board reviewed adverse events and serious adverse events on a blinded (Group A / Group B) basis. The DSMB recommended continuing the trial.

On 17th of November, 1326 patients were randomized (55 % of the calculated sample size) in the study. Thereby the PROTHOR trial is already the largest trial on mechanical ventilation in thoracic anesthesia ever! By reaching the total sample size, the PROTHOR trial will be the largest trial on mechanical ventilation ever conducted. We are confident to reach this goal together with you. Currently we have 80 registered centers working on the study and the number of centers is still increasing. We thank you for your untiring commitment in the study.



The PROTHOR Randomized Controlled Trial

Overview of randomized patients over time

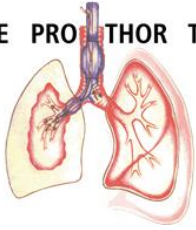


Completeness of datasets and new trial coordinator

We have noticed that several datasets are not complete although the time for follow up (90 days after randomization) has already passed. Please complete all datasets in a timely manner, this will help us with database monitoring and improve data quality. All of you will continue to receive database review reports from Philipp Kamratowsky (study nurse), Katharina Birr and Niklas Melchior (study monitors) asking you to complete your datasets.

Jakob Wittenstein will be taking over from Thomas Kiss, who changed the workplace, as Trial Coordinator. Please direct all questions regarding the study to him in the future (jakob.wittenstein@ukdd.de). Thomas Kiss will continue to be involved in the study as an active member of the Steering Committee.

Best regards to all and stay safe,



The PROTHOR Randomized Controlled Trial

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