Author's response to reviews

Title: Prothrombin Complex Concentrate in the Reduction of Blood Loss during Orthotopic Liver Transplantation: PROTON-trial

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Author's response to reviews:

Dear Editor,

We thank you for considering our manuscript for BMC surgery.

Please find enclosed in the resubmission of our manuscript of the study protocol of the PROTON- trial: ‘Prothrombin complex concentrate in the reduction of blood loss during orthotopic liver transplantation’.

Also, here follows the point-by-point description of the changes made in the manuscript:

- We have recently obtained approval from the Medical Ethical Committee of the University Medical Center Groningen, as described in the study protocol (Ethical Considerations page 14 of the manuscript). The study has not yet been approved for the centers in Belgium or Finland for which we are still waiting. We feel that it is important to submit this study protocol for peer review since this randomized trial will deal with the relevance of using prothrombin complex concentrates in liver transplantation and the relevance of correcting preoperative INR in liver transplant candidates. Many centers use prothrombin complexes concentrates during liver transplantation, while the efficacy has never been demonstrated in a randomized trial. Other centers are hesitant out of fear for thrombotic complications. We feel that the PROTON trial is potentially a landmark trial that
will settle this issue and feel it is relevant to publish the study protocol prior to initiation.
- The study is not externally funded.
- The study has received funding from a semi-commercial organization, Sanquin Blood Supply Foundation. We have provided this information in the Competing Interest section on page 17 of the manuscript.
- The manuscript is in English.
- There are no manuscripts under submission with other journals based on this study protocol.
- The trial is registered at www.trialregister.nl, which is a registry accepted by the ICMJE. We have added this comment to the abstract.
- We have included more information in the section Methods/Design of the abstract.

We hope you will find our manuscript suitable for publication in its current form.

Yours Sincerely,

Professor R.J. Porte, M.D. Ph.D., surgeon
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