Author's response to reviews

Title: Methodology of the Prospective Economic Evaluation of the Prophylaxis for ThromboEmbolism in Critical Care Trial (E-PROTECT)

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Study protocol
Methodology of the Prospective Economic Evaluation of the Prophylaxis for ThromboEmbolism in Critical Care Trial (E-PROTECT)


Trials

Dear Dr Fowler,

Thank you for submitting your study protocol to Trials.

Before your manuscript can be sent to our Editorial Board for their initial consideration, please could you provide us with copies of the original funding and ethics documentation. We would very much appreciate it if you could provide these in English, or provide translations to accompany the original documents.

We need to confirm the following:

- that the documentation refers to the correct study and we can tell which body granted the approvals
- that full ethical approval has been given (i.e. not with conditions)
- if funding is external (from a government/research organisation)

Please could you email the documentation to us. We encourage you do this as soon as possible to minimise any delay to the processing of your manuscript.

>Thank you. The full ethics approval has been attached to this email.

>Funding documentation from the Heart and Stroke Foundation, the University of Toronto, and the Canadian Intensive Care Foundation is attached to this email.

We also have a few editorial requests we would like you to address at this stage:

Please include the trial registration number at the end of your abstract. If your research article reports the results of a controlled health care intervention, please list your trial registry, along with the unique identifying number.

> We have positioned the trial registry of the controlled health care intervention which we report (PROTECT) at the end of the abstract.

2. As your research involves humans please include a statement of ethical approval in the Methods section of the manuscript, including the name of the body which gave approval, with a reference number. Any experimental research on humans must be in compliance with the Helsinki Declaration. If your study is taking place in multiple sites please ensure you mention all of the ethical bodies
that have approved the study at the different sites.

> We have included the following sentence: "Research ethics approval for E-PROTECT was granted by Sunnybrook Health Sciences Centre (project identifier 115-2007)."

3. Please include a statement in your Methods section explaining that you obtained informed consent from each participant.

> We have added the sentence: "Informed consent was obtained from each participant in PROTECT, or their substitute decision-maker, in accordance with local research ethics approvals."

4. Please include a trial status section below your Discussion. This should state the status of the trial at the time of manuscript submission. The journal considers study protocol articles for proposed or ongoing trials provided they have not completed patient recruitment at the time of submission.

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5. Please include an Authors’ Contributions section at the end of the manuscript, before the reference list. Each author needs to be listed individually. We suggest the following kind of format (please use initials to refer to each author's contribution):

Authors’ Contributions
EP: conception and design, data collection and analysis, manuscript writing and final approval of the manuscript. SP: data collection and analysis, critical revision and final approval of the manuscript. MG: data collection and analysis, critical revision and final approval of the manuscript. AP: data collection and analysis and final approval of the manuscript. LS: data collection and analysis and final approval of the manuscript. MCL: data collection and analysis and final approval of the manuscript. FB: conception and design, financial support, manuscript writing, final approval of manuscript. XH: conception and design, data collection and analysis, manuscript writing, final approval of the manuscript. All authors read and approved the final manuscript.

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> We have removed this section and relabelled with the heading Discussion

Once you have made the changes detailed above, upload your revised manuscript and we can proceed with your submission.

>Thank you very much. We have uploaded the reviewed manuscript.

Please do not hesitate to contact us should you have any questions.

Best wishes,

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