Author's response to reviews

Title: Study protocol for a randomized, double-blind placebo-controlled trial of a single preoperative steroid dose to treat nausea and vomiting after thyroidectomy: the tPONV study

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Author's response to reviews:

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St. Gallen, February 8th, 2013

Re-submission – MS: 563805599885452: Study protocol for a randomized, double-blind placebo-controlled trial of a single preoperative steroid dose to treat nausea and vomiting after thyroidectomy: the tPONV study

Dear Mrs. Costoy

Enclosed please find the re-submission of the manuscript entitled:

"Study protocol for a randomized, double-blind placebo-controlled trial of a single preoperative steroid dose to treat nausea and vomiting after thyroidectomy: the tPONV study".
In the following we will respond to the issues raised in your e-mail. All changes in the revised manuscript are highlighted in bold, italics and underline.

All authors have read and approved the amended version of the manuscript. Thank you for your time and consideration of our revised manuscript.

Sincerely yours,

Iganzio Tarantino, MD, MSc, on behalf of all authors

1. “Thank you for considering BMC Anesthesiology for your manuscript. As you may be aware, it is the policy of the journal not to peer review study protocols where ethical and external funding approval have been obtained, as these processes usually involve peer review and as there is little possibility to change a protocol after enrolment begins. Therefore, could you please clarify whether you have ethical approval and external funding for your study, and if so, could you send evidence of your approvals to the address below?”

The study was approved by the Ethics Committee of the Canton of St. Gallen (Ethikkommission des Kantons St. Gallen, reference number EKSG10/082/2B) as well as by Swissmedic (reference number 2011DR3005). Please find attached the proof of ethical approval. Furthermore, we received a grant for the study from a governmental funding source (Clinical Trial Unit of the Cantonal Hospital of St. Gallen, http://www.mfz.kssg.ch/home/unser_fachbereich/ctu.html). We did not receive funding from a commercial organization. The total amount of funding is CHF 34'888. We attached the proof of funding (amount of funding is stated on the first page).

2. “A study is considered to be externally funded if the authors have been awarded a grant for the study by a major funding body (e.g. governmental funding/ award from a charitable foundation). If a study has not received external funding, then the study protocol will be sent for peer-review with a member of our Editorial Board.

If a study has received funding/assistance from a commercial organization, this should be clearly stated in the ‘competing interests’ section of your manuscript, and the study protocol will be sent for peer-review by a member of our Editorial Board.”

Please see answer to point 1.

3. “If your documents are not in English, please could you provide translated versions of the relevant parts. These should be endorsed and signed by a contactable person at the institution. Please also include the original documents“.

The letter of approval (ethical approval and grant approval) was issued in English as well as in German from the corresponding authority. We attached a copy of the English version of both ethical and grant approval signed by the responsible authority.
4. “N.B. Proof of external funding should include details of the amount of funding that was awarded for your study.“

As outlined under point 1 we received a total amount CHF 34’888. Please see attachment “grant approval” (The amount and annual funding can be found on page 1).

5. “Could you also provide a list of any manuscripts that are under submission with other journals based on this study protocol?”

No other manuscripts have been submitted based on this study protocol. As the study is still ongoing only the present manuscript was submitted to BMC Anaesthesiology.

6. “BioMed Central requires all controlled clinical trials to be registered in a suitable publicly accessible registry prior to consideration for publication. The trial registers that currently meet all of the ICMJE guidelines can be found at http://www.icmje.org/faq.pdf.“

The study was registered on July 19th, 2010 at www.clinicaltrials.gov under the trial identification number NCT01189292.

7. “The Executive Editor has also requested for you to include the following:
   Thank you for including an ethics statement in your manuscript. However, we would ask you to include the full name of the committee that approved your study in this statement.”

We made the corresponding change. The change is highlighted in the revised manuscript.

Before:

This protocol, the patient information sheet and the patient consent form have been reviewed and approved by the local Ethics Committee and by Swissmedic prior to enrolling any patients in this trial.

After change:

This protocol, the patient information sheet and the patient consent form have been reviewed and approved by the Ethics Committee of the Canton St.Gallen (EKSG10/082/2B, http://www.sg.ch/home/gesundheit/ethikkommission.html) and by Swissmedic (2011DR3005, http://www.swissmedic.ch/index.html?lang=en) prior to enrolling any patients in this trial.