Author's response to reviews

Title: Randomized controlled trial to evaluate the effects of ethyl-2-cyanoacrylate on pain intensity and quality of life in head and neck cancer patients suffering from cetuximab-induced rhagades during radioimmunotherapy: The SUPPORT Trial

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Version: 3  Date: 9 October 2012

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Randomized controlled trial to evaluate the effects of ethyl-2-cyanoacrylate on pain intensity and quality of life in head and neck cancer patients suffering from cetuximab-induced rhagades during radioimmunotherapy: The SUPPORT Trial

Karin Potthoff, Gergor Habl, Thomas Bruckner, Christian Suppan, Jessica Hassel, Dirk Jaeger, Martin Indorf and Juergen Debus

Dear Editor,

enclosed, please find the revised version of the above listed manuscript suggested for publication in BMC Cancer.

In the following I would like to address and respond to the points made by the reviewers.

1) **Request for abstract section.**
The Abstract of the manuscript should not exceed 350 words and must be structured into separate sections: Background, the context and purpose of the study; Methods, how the study was performed and statistical tests used; Results, the main findings; Conclusions, brief summary and potential implications. Please minimize the use of abbreviations and do not cite references in the abstract. Trial registration, if your research article reports the results of a controlled health care intervention, please list your trial registry, along with the unique identifying number (e.g. Trial registration: Current Controlled Trials ISRCTN73824458). Please note that there should be no space between the letters and numbers of your trial registration number. We recommend manuscripts that report randomized controlled trials follow the CONSORT extension for abstracts.
Answer: I made minor changes. The abstract now comprises 344 words (before 346 words) and it is structured according to the recommendations for a "study protocol" in your journal, i.e. Background, Methods/Design, Discussion. The article type is “study protocol”. The unique identifying number is a number von Clinicaltrials.gov.

2) **Request for ethical and funding proofs.

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?

- 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.
- 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.
- N.B. Proof of external funding should include details of the amount of funding that was awarded for your study.

Answer:

Attached you will find the ethics document in German. We received the ethics approval on February 28th, 2011.

IOMEDICO AG is the clinical research organization which, on the authority of the sponsor, i.e. the University of Heidelberg Medical Center, is responsible for questionnaire logistics and eCRF programming. All the other study logistics will be carried out by our own.
The SUPPORT study is not funded by an external funding body or a commercial organization. It is an investigator initiated trial without external funding done by intramural, i.e. internal support within the University of Heidelberg Medical Center. Therefore I did not mention “Acknowledgement” for funding of the study in the paper.

3) Could you also provide a list of any manuscripts that are under submission with other journals based on this study protocol?

Answer: There are no other submissions.

4) 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.

Answer: The trial is registered at clinicaltrials.gov, NCT01693159.

Best regards,

Karin Potthoff