Author’s response to reviews

Title: A multi-centre, non-inferiority, randomised controlled trial to compare a cervical pessary with a cervical cerclage in the prevention of preterm delivery in women with short cervical length and a history of preterm birth - PC Study

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Dear dr. Nawsheen Boodhun,

Thank you for considering our study protocol, A multi-centre, non-inferiority, randomised controlled trial to compare a cervical pessary with a cervical cerclage in the prevention of preterm delivery in women with short cervical length and a history of preterm birth – PC Study,
for publication in BMC Pregnancy and Childbirth. Please find below our response to your questions and comments.

1. Ethical and Funding Approval Documentation. Before we can proceed with your submission, can you please forward copies of all ethical approval and funding approval for our records. These documents should be sent as email attachments to the following email address, BMCSeriesEditorial@biomedcentral.com. Please DO NOT upload these documents as additional files in the submission system. 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. Can you please confirm in your cover letter that you have forwarded the requested documentation to BMCSeriesEditorial@biomedcentral.com.

Response: We have forwarded the requested documentation to BMCSeriesEditorial@biomedcentral.com. Please do not hesitate to contact us should you require more documents.

2. Funding

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. Can you please confirm whether your study protocol has undergone peer-review by the funding body.

Response: The PC Study is funded by The Netherlands Organization for Health Research and Development (ZonMw), a national organisation that promotes quality and innovation in health research and health care, initiating and supporting new developments. ZonMw sends all applications to reviewers to assess quality of applications. (please see also:


3. Study status
The protocol must be for a study that is ongoing. An ‘ongoing’ study is defined as one where the investigators are still collecting, or analyzing data. Can you please confirm what stage your study is currently at.

Response: The PC Study is currently recruiting women for participation in the study.

4. Related Articles

Can you please clarify whether any publications containing the results of this study have already been published or submitted to any journal. If so, can you please provide a list of the related articles.

Response: There are no publications containing (preliminary) result of the PC Study.

5. Can you please provide clarification on whether the ethics approval obtained from the medical ethics committee of the Academic Medical Centre Amsterdam is an umbrella approval which covers all of the participating sites or not? If not, were separate ethics committees approached for the other sites?

Response: Ethics approval from the medical ethics committee of the Academic Medical Center Amsterdam is an umbrella approval which covers all of the participating sites.

The Central Committee on Research Involving Human Subjects In The Netherlands (Dutch: Centrale Commissie Mensgebonden Onderzoek: CCMO) states as follows:

‘In the multicentre procedure no role has been created for the local (medical ethical) committees of the local participating centres. Therefore, an MREC of a participating centre may not again review a protocol after it has already been reviewed by another MREC. So in the case of multicentre research (and external monocentre research), MRECs of participating centres may not carry out a WMO review.’ (source: http://www.ccmo.nl/en/multicenter-research)

We appreciate your time and look forward to your response.

Sincerely yours,

Also on behalf of the study group and all co-authors,

Bouchra Koullali, MD