Author's response to reviews

Title: Early salpingectomy (TUbectomy) with delayed oophorectomy to improve quality of life as alternative for risk-reducing salpingo-oophorectomy in BRCA1/2 mutation carriers (TUBA study): a prospective non-randomised multicentre study

Authors:

Marline G Harmsen (Marline.Harmsen@radboudumc.nl)
Marieke Arts-de Jong (Marieke.Arts-deJong@radboudumc.nl)
Nicoline Hoogerbrugge (Nicoline.Hoogerbrugge@radboudumc.nl)
Angela HEM Maas (Angela.Maas@radboudumc.nl)
Judith B Prins (Judith.Prins@radboudumc.nl)
Johan Bulten (Hans.Bulten@radboudumc.nl)
Steven Teerenstra (Steven.Teerenstra@radboudumc.nl)
Eddy MM Adang (Eddy.Adang@radboudumc.nl)
Jurgen MJ Piek (JPiek@tsz.nl)
Helena C van Doorn (H.vanDoorn@erasmusmc.nl)
Marc van Beurden (M.v.Beurden@nki.nl)
Marian JE Mourits (M.J.E.Mourits@umcg.nl)
Ronald P Zweemer (R.Zweemer@umcutrecht.nl)
Katja N Gaarenstroom (K.N.Gaarenstroom@mumc.nl)
Brigitte FM Slangen (Brigitte.Slangen@mumc.nl)
Maria C Vos (C.Vos@elisabeth.nl)
Luc RCW van Lonkhuijzen (L.R.vanLonkhuijzen@amc.uva.nl)
Leon FAG Massuger (Leon.Massuger@radboudumc.nl)
Rosella PMG Hermens (Rosella.Hermens@radboudumc.nl)
Joanne A de Hullu (Joanne.deHullu@radboudumc.nl)

Version: 2 Date: 3 July 2015

Author's response to reviews: see over
Dear Editor,

In response to your e-mails dated 11th, 17th, 18th and 19th June 2015, we are very glad to be able to provide you with the requested answers and documentation concerning our manuscript of the study protocol 'Early salpingectomy (TUbectomy) with delayed oophorectomy to improve quality of life as alternative for risk-reducing salpingo-oophorectomy in BRCA1/2 mutation carriers (TUBA study): a prospective non-randomised multicentre study' (MS ID: 8633769531748615).

Thank you very much for your patience and for your additional questions. Our responses to your requests are written below. The additional information does not require changes to the manuscript, unless one or more of the following should be stated in the manuscript as well.

#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, BMC.Series.Editorial@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 BMC.Series.Editorial@biomedcentral.com.
1) The Medical Ethics Review Committee responsible for judging all studies initiated in the Radboud University Medical Center provided us with an English letter confirming medical ethical approval in all participating centres. We forwarded this letter to BMCSeriesEditorial@biomedcentral.com.

2) The Dutch Cancer Society (Dutch: KWF Kankerbestrijding) is a charitable foundation. The TUBA study was awarded with a KWF grant in December 2014 after peer-review by three international reviewers from its scientific council (Dutch: Wetenschappelijke Raad, or WR). We forwarded the grant approval letter in Dutch to BMCSeriesEditorial@biomedcentral.com. We could not obtain a full English version at short notice, but we will translate the paragraphs stating the approval. The reviewers’ comments are already in English in the original letter. Hopefully this satisfies the request.

We have pleasure in announcing you that the Dutch Cancer Society, based on the advice of the Scientific Council, decided to fund your project for a maximum of the (full) project duration, as stated in the supplementary advice.

(...)

Advisering van de WR in zake de toegekende subsidie treft u aan in het aanvullend advies. Het totaal toe te kennen bedrag bedraagt € 469,900,--. Recommendations of the Scientific Council concerning the awarded grant is stated in the supplementary advice. The total awarded grant amounts € 469,900.

#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.

As explained in our answer to request #1, the study is funded by the Dutch Cancer Society, a charitable foundation, after peer-review by three international reviewers (project number KUN 2014-7187). Their comments and recommendations (in English) are added to the letter of the Dutch Cancer Society dated 22nd December 2014. This letter is forwarded to BMCseriesEditorial@biomedcentral.com.

#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.

We hereby confirm that the TUBA study has started in January 2015 and is ongoing.

#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.

No publications containing any (preliminary) results of the TUBA study have already been published or submitted to any journal.

Neither the manuscript, nor a substantial part of the data have been published previously and these are not currently under consideration for publication elsewhere. All authors have read the manuscript and agreed to its content. None of the authors have to declare any conflicts of interest.

Please consider the following individuals as peer reviewers:
Karen H. Lu, M.D. Professor and Chair of Gynecologic Oncology at MD Anderson Cancer Center, Houston, Texas, United States. E-mail: khlu@mdanderson.org
Janice S Kwon, Assistant professor of Gynecologic Oncology, University of British Columbia, Vancouver, British Columbia, Canada. E-mail janice.kwon@vch.ca
Eric Leblanc, Surgeon and Head of the department of Gynecological Oncology Centre Oscar Lambret-Lille, France. E-mail e-leblanc@o-lambret.fr
I look forward to hearing from you.

Yours sincerely,

Marline Harmsen (M.D.), corresponding author