Author’s response to reviews

Title: The (cost) effectiveness of procedural sedation and analgesia versus general anaesthesia for hysteroscopic myomectomy, a multicentre randomised controlled trial: PROSECCO trial, a study protocol

Authors:

Julia van der Meulen (juliavandermeulen@gmail.com)
Marlies Bongers (m.bongers@mmc.nl)
Sjors Coppus (Sjors.C Coppus@mmc.nl)
Judith Bosmans (j.e.bosmans@vu.nl)
José Maessen (Jose.maessen@mumc.nl)
Katrien Oude Rengerink (koudere2@umcutrecht.nl)
Lucilla Overdijk (l.e.overdijk@olvg.nl)
Celine Radder (c.radder@olvg.nl)
Lucet van der Voet (l.vandervoet@dz.nl)
Nicole Smeets (n.smeets@zuyderland.nl)
Huib van der Vliet (Huib.v.vliet@catharinaziekenhuis.nl)
Wouter Hehenkamp (w.hehenkamp@vumc.nl)
Arentje Manger (pmanger@diakhuis.nl)
Wilbert Spaans (Wilbert.spaans@mumc.nl)
Erica Bakkum (E.A.Bakkum@olvg.nl)
Nicole Horrée (nhorree@flevoziekenhuis.nl)
Justine Briët (j.briet@zgt.nl)
Jan Willem van der Steeg (j.v.d.steeg@jbz.nl)
Helen Kok (hskok@alrijne.nl)
Author’s response to reviews:

Dear Editor,

We are very grateful for you to provisionally recommend the manuscript “The (cost) effectiveness of procedural sedation and analgesia versus general anaesthesia for hysteroscopic myomectomy, a multicentre randomised controlled trial: PROSECCO trial, a study protocol” (BMWH-D-18-00304), for acceptance in BMC Women’s Health.

We have revised our manuscript according to the comments in your email of 27 November 2018.

In this letter we will explain which amendments have been made to the manuscript text and where they can be found.

1. Please reduce the overlap with the consortium interface http://studies-obsgyn.nl/home/page.asp?page_id=1686 and Herman MC et al, BMC Women’s Health (2013)

The consortium interface http://studies-obsgyn.nl/home/page.asp?page_id=1686 is a website providing information on the PROSECCO study, which was created by our own study group. The information provided on the website is based on our study protocol. Hence overlap is inevitable and cannot be reduced.

To reduce overlap with Herman MC et al, BMC Women’s Health (2013) a few sections and lines were rewritten:

- Methods section, trial design and setting, line 136, page 6
- Methods section, data collection, line 211 – 217, page 9-10
- Declarations section, competing interests, line 371, page 16
- Declarations section, author’s contributions, line 381, page 16

2. Please ensure these email addresses on the title page match the email addresses provided in the editorial manager system.

The email addresses on the title page were checked and match the email addresses provided in the editorial manager system.

3. Please move all the tables out of the results section and place them after the References in a section called "Figures, tables additional files".
After the references a ‘figures, tables and additional files section was created and table 1 was moved from the results section hereto. “Figures, tables, additional files section, line 461 – 479, page 21-22”

4. Please include a paragraph each on the inclusion and exclusion criteria for recruitment for the trial

The eligibility criteria section was rewritten and an inclusion and exclusion criteria paragraph was included.

“Methods, eligibility criteria section, line 142-155, page 7”

5. Please re-word ‘List of Abbreviations’ to read ‘Abbreviations’

Re-worded as requested. “Abbreviations section, line 332, page 15”

6. Please include the text stated within the ‘Ethics consideration’ heading in the ‘Ethics approval and consent to participate’. Please state if written or verbal consent will be sought within this sub-heading in the declarations.

The text stated in the ‘ethics consideration’ heading was removed from the main text and included in the ethics approval and consent to participate section. It was stated that written consent for participation will be obtained. “Declarations section, ethics approval and consent to participate, line 347 – 362, page 15-16”

7. Please re-word ‘Methods/Design’ to read ‘Methods’

Re-worded as requested. “Methods section, line 123 page 6”

8. In the Authors' contributions section, the individual contributions of each author should be specified. Please use initials to refer to each author's contribution in this section.

The contribution of all authors was specified. “Author’s contributions section, line 378-382 page 16”

9. Can you please clarify the roles of authors SC, JM, LvdV, NS, HvV, WH, AM, WS, EB, MH, JB and JvdS in the design, execution and analyses of the presented study? Please make sure all authors qualify for authorship. Guidance and criteria for authorship can be found in our editorial policies at https://www.biomedcentral.com/getpublished/editorial-policies#authorship.
The contribution of all authors was specified. “Author’s contributions section, line 378-382 page 16”

We hope that the above described amendments meet your requested revisions and we would be most grateful when our manuscript would be accepted for publication.

Yours Faithfully,

On behalf of all co-authors,

Julia F. van der Meulen