Author's response to reviews

Title: Comparison of the effectiveness of low pressure pneumoperitoneum with profound muscle relaxation during laparoscopic donor nephrectomy to optimize the quality of recovery during the early post-operative phase: study protocol for a randomized controlled clinical trial

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

We would like to thank the reviewers for their useful comments. Below a point-by-point response to the comments of the reviewers.

Reviewer 1:

1. I remain concerned about the apparent lack of statistician involvement in this trial. Although I am not a statistician, my understanding is that if using stratification, these factors should be taken into account in the statistical analysis. All trials should have adequate statistician involvement, preferably from a statistician with experience of trials. The use if the SD of 14 remains inadequately justified.

Reply: We thank the reviewer for his valuable suggestions. A statistician (Rogier Donders) addressed the issues raised by the reviewer. As the statistician contributed substantially he is now added as co-author (please see page 1, line 8 and 27).

We agree with the reviewer that a students’ t-test is not appropriate to control for the variables used for stratification. We have therefore changed the section regarding statistical analysis: “Since we stratify for gender and side of donor nephrectomy, factorial ANOVA with a custom design will be used for statistical analysis.”(page 9, line 224).

To estimate a standard deviation for the quality of recovery, only one paper is available providing data after laparoscopic surgery (18). De Oliviera et al. studied the quality of recovery in patients undergoing laparoscopic hysterectomy. The QOR-40 at postoperative day 1 ranged from 136 to 190 in this study, which provides an estimated SD of 13.5. Therefore we feel that a SD of 14 is justified.

As the group of living kidney donors is highly homogeneous, we do not expect that the variation in quality of recovery is higher as compared to patients undergoing laparoscopic hysterectomy.

We changed the Methods section accordingly: “For other procedures, standard deviation of QoR-40 scores varies between 12 and 23 points with one study investigating the QoR-40 score after laparoscopic surgery. Data from this study indicate a standard deviation of 14 in patients after laparoscopic hysterectomy. As the group of living kidney donors is highly homogeneous, we do not expect a higher variation in the quality of recovery as compared to patients after laparoscopic hysterectomy. Therefore, we used a standard deviation of 14 for the sample size calculation.” (page 9, line 217)

Reviewer 2:

1. The revision has been improved and addresses my comments and concerns satisfactorily.

Reply: We thank the reviewer for his/her endorsement.

All editorial requests have been incorporated in the manuscript. We thank you for your time and consideration for publication.

Kind regards,

Denise Özdemir-van Brunschot, MD PhD student
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