Author's response to reviews

Title: Pit excision with phenolisation of the sinus tract vs. radical excision in sacrococcygeal pilonidal sinus disease: study protocol for a single centre randomized controlled trial

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Trials

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Dear editor,

We would like to thank you for the opportunity to revise and resubmit our manuscript “Pit excision with phenolisation of the sinus tract vs. radical excision in sacrococcygeal pilonidal sinus disease: study protocol for a single centre randomized controlled trial”, to Trials after careful revision of the original manuscript.

We have appreciated the constructive comments of the reviewers on the original paper. We have incorporated their remarks which elevated the quality of the manuscript. Please notice our remarks and adaptations of the manuscript with reference to the comment of the reviewers. We will discuss each item of the reviewers’ comments point-by-point from the next page of this cover letter. The adaptations of the text are highlighted in the revised manuscript.

We truly hope that the manuscript will be suitable for publication in Trials to your
opinion.

All authors are fully conversant with the revised manuscript.

Should you have any further questions regarding the revised version, please contact us through the aforementioned contact information.

Sincerely yours,

E.J.B. Furnée, MD, PhD
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Reviewer #1:

Thank you for your comment.

Ad 1:
We have made the following changes and added details regarding our study methods according to the SPIRIT guideline:
- The sequence in the methods/design section has been changed according to the one proposed by the SPIRIT guideline
- We have changed the title (page 1) and description of the study design (page 8, line 4-5)
- Information regarding the recruitment of participants has been added in a separate paragraph on page 12, line 15-24
- We have adjusted and extended the paragraph on Randomization (page 13, line 1-9)
- We have added information with regard to “blinding” (page 13, line 11-14)
- A paragraph on data collection has been added (page 13, line 16 – page 15, line 3)
- We have described our proposed statistical analysis in the paragraph on statistical methods (page 15, line 5-18)
- The heading of the safety paragraph has been changed in “Harms” (page 15, line 20)
- We have extended the information on Ethics (page 16, line 9-12)

Ad 2:
We have added the current status and provisional end date of the study on page 20.
On request of the third reviewer, we have also added this at the end of the abstract (page 3).
Ad 3:
We have added the reason for not blinding in a separate paragraph on page 13, line 11-14.

Ad 4:
We have added information regarding our proposed statistical analysis (page 15, line 5-18).

Ad 5:
We really appreciate that you have indicated that our primary outcome measure was too vaguely described. We have clarified our primary outcome measure “return to normal activities” in the manuscript (page 10, line 25 – page 11, line 4). We have added what we mean by “return to normal activities” en how it is assessed.

Ad 6:
We have changed all tenses in the present simple tense throughout the manuscript.

Reviewer #2:

Thank you very much for your suggestion to perform the cleft lift procedure in the control arm in this randomised controlled trial. Indeed, this is an interesting and successful procedure in patients with chronic sacrococcygeal pilonidal sinus disease and was also considered as the treatment of choice in the control group. However, the Karydakis procedure is, in our opinion, currently the most applied treatment in patients with sacrococcygeal pilonidalis sinus disease. Therefore, we preferred to compare phenolisation of the sinus tract with the Karydakis procedure. However, a randomised controlled trial comparing phenolisation with the cleft lift procedure will be very interesting for further research after the completion of the current, on-going randomised trial.

Reviewer #3:

Thank you for your comment.

We have extensively changed the manuscript according to the SPIRIT guideline. The changes we have made are described in the comment to reviewer 1. We have adapted your comments in the attached revised manuscript and will response to your comment point-by-point:

Ad 1:
We have added these two words in the abstract (page 2, line 5).

Ad 2:
We have replaced “long” by “longer” (page 2, line 12)
Ad 3:
We agree that it was not clear how en by whom the primary and secondary outcome measures were assessed. We have added information regarding the assessment of the primary and secondary outcomes in the main text (page 10, line 23 – page 11 line 12). However, we could not add this in the abstract as this is restricted to a word count.

Ad 4:
The current status of the trial has been added at the end of the abstract (page 3, line 8-9) as well as at the end of the manuscript (page 20). Recruiting has currently not been completed and this is an ongoing trial.

We can imagine that it might not be clear from the CONSORT figure that this is an ongoing trial. Therefore, we have added “Assumed” to “to do not meet randomisation criteria” and “refusal to participate”. Both values are assumptions used to calculate the total number of patients to be assessed for recruitment to achieve the total number of patients required for this trial.

Ad 5:
Indeed, watchful waiting is the preferred term here, so we have replaced “observation” by “watchful waiting” (page 5, line 9).

Ad 6:
References have been provided in this sentence on page 5, line 13-14.

Ad 7:
All SD’s were placed in round brackets throughout the manuscript.

Ad 8:
The reference was added to the review mentioned here in the manuscript (page 6, line 10). The number of the reference has been changed (13 instead of 10) due to reference changes in line 13-14 on page 5 (see answer at point 6).

Ad 9:
“Ranged” has been replaced by “varied” in line 16 on page 6.

Ad 10:
“And/or” has been replaced by “or” in line 19 on page 12.

Ad 11:
The word “significantly” has been replaced by “considerably” in line 20 on page 12.

Ad 12:
In line 13 on page 8, “In order to” has been replaced by “To”.
Ad 13 and 14:
A full stop has been added on page 8 in line 16 and 24.

Ad 15:
We fully agree that the description of randomisation in the original manuscript was very restricted and therefore inadequate. We have extended the paragraph on “Randomisation” according to the method we randomise patients in this trial (page 13, line 2-9).

Ad 16:
Return to normal activities will be decided by the patient. The patients are not medically restricted after both interventions. However, complaints after the surgical procedure will restrict patients to do normal activities. The loss of days of normal activities is assessed by a patient’s diary after surgery. Unfortunately, blinding of the patient and assessor is not possible, as in most surgical trials, because of the obvious differences between both interventions. However, the hypothesis and primary outcome measure is unknown for patients. These comments regarding the primary endpoint and blinding are added in the manuscript (page 10, line 25 – page 11, line 4 and page 13, line 12-14).

Ad 17:
We have summarised the secondary end-points one-by-one on page 11. The method of scoring and interpretation of these secondary outcome measures has been extensively described in an additional paragraph on data collection that we have added on page 13, line 16 – page 15, line 3.

Ad 18 and 19:
References have now been provided for these statements (page 15, line 21 and line 23).

Ad 20:
Thank you for your comment that this statement was wrongly described. We have stated now in this sentence that no serious adverse events were reported in the referred studies (page 15, line 23).

Ad 21:
“Registered” has been replaced by “recorded” (page 15, line 24).

Ad 22:
The values from the literature are cited (adopted from the description in the introduction) and provided with references (page 12, line 10-11).

Ad 23:
Microsoft Excel was used to compute the sample size and this was added in line 12-13 on page 12.
Ad 24:
“Years” was correctly referred here, but “one” was not and is therefore replaced by “two” (page 12, line 24). As 130 patients with pilonidal sinus disease were presented in two years (2011 and 2012) in our hospital, the inclusion period for 100 patients required in this trial will be about two years.

Ad 25:
- We have more extensively described what we mean by the ITT principle (page 15, line 6-7)
- A reference has been added for the intention to treat principle (page 15, line 7)
- Additionally, we have added that we will report the withdrawals from each randomisation group and that we will perform a sensitivity analysis to measure the effect of missing data on the outcome (page 15, line 16-18). We have used your suggested reference for these additions to the manuscript and this has also been added to the reference list.

Ad 26:
“Exist” has been replaced by “consist of up” (page 11, line 20).

Ad 27:
We have replaced “approximated” by “closed” (page 10, line 16).

Ad 28:
There is no specific date as of when the phenolisation procedure has increasingly been applied, this has gradually increased. This increase started about five years ago. This has been changed on page 17, line 3.

Ad 29:
We agree with your comment and have added “as far as we know” in line 10 on page 17.

Ad 30:
We have also added references with regard to this point on page 17, line 22.

Ad 31:
This part of the discussion has been changed (page 17, line 24 – page 18, line 4).

Ad 32:
A reference has been added to this statement, page 18, line 7.

Ad 33:
“Is” has been replaced by “may be” (page 18, line 17). The decision to repeat the phenolisation procedure is depending on both the anatomical recurrence of SPSD and the influence of the complaints related to the recurrence on the quality
of life. This has been described in the study protocol in line 18-20 on page 11.

Ad 34:
We have included one third of the calculated sample size and recruiting has currently not been completed. This is an on-going trial and therefore, we do not have the results at this moment.
See also our response to your comment 4.

Ad 35:
This person gives his input regarding methodology and statistical questions with regard to all the research projects we perform in our department. If his contribution to a manuscript is considerable and meet the criteria to be an author as stated by most publishers, just like Trials, then he will be a co-author of the manuscript. If he does not meet these criteria, like in this case, we will acknowledge him.

Ad 36-40:
The changes in the references have been made in the reference list.