Reviewer's report

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

Version: 2

Date: 4 November 2014

Reviewer: Charlie Goldsmith

Reviewer's report:

This manuscript should have followed the SPIRIT guidelines in its construction. There are many issues in trial design that are currently deficient and should be dealt with. The authors should consider adding a trial methodologist to their team to improve this manuscript. More specific comments follow:

1. P(age) 2, l(ine) 5. Insert [patients with] between [for] and [sacroccygeal].
2. P 2, l 12, Add [er] to read [longer].
3. P 2, l 22 and 23. Who decides these outcomes?
4. P 3, l 8. Include the date the first patient was randomized. Also from Figure 2, it appears the trial has completed recruiting. When was the last patient randomized, and if the study is completed, when was the last measurement of outcome made? Specify these dates in the same date format here.
5. P 5, l 9. What does the [observation should] mean. Is this another term for watchful waiting?
6. P 5, l 13. Insert [[6]] after [Miller]. Also include R(eference)s for the other methods in these lines.
7. P 5, l 25. Delete [±} in front of SD. This is no longer a good method. Simply put the SD in round brackets after the mean. There are other places in the text that should also be done, but will not be noted.
8. P 6, l 10, Insert [[10]] after [2009].
10. P 8, l 13. Since [or] logically includes [and], delete [and/].
11. P 8, l 14. Replace [significantly] by [usually] or some other word. Save significant for its statistical context.
12. P 8, l 17. Delete [In order] and capitalize [To] as the words are redundant in English.
15. P 9, l 7 to 9. This description is not adequate for a randomization. If you are using opaque envelopes they must be opened one at a time and what is contained in them should be described. See C Meinert’s book on clinical trials,
page 86 to see how to describe a randomization strategy.

16. P 9, l 12 and 13. The person who will decide this should be blind to
treatment. Is this so? The type of person should be named.

17. P 9, l 16 to 21. These outcome measures are not adequately described.
Apart from references, the scales of each should be described, how they are
scored and how they are interpreted, along with their measurement properties
such as reliability, validity and responsiveness.

18. P 9, l 25. Provide a R.

19. P 10, l 9. Provide Rs for these.

20. P 10, l 10. Without a search strategy, this statement is vacuous.


22. P 10, l 17. These values should be cited and from which studies should have
Rs.

23. P 10, l 14 to 22. What software was used to compute the sample size? It
should be cited if used.


25. P 10, l 25. ITT should be cited. At the moment this analysis is inadequate and
does not properly consider all the variables, assumptions and models to be used
in the analysis. What will be done if there are missing data? Your statement is
not credible (on l 22). See Little RJ et al in the 2012 Oct 4 NEJM to prevent and
analyse missing data if they happen.


27. P 12, l 24. Would [closed] be a better word than [approximated].


29. P 14, l 11 and 12. Either provide a credible search strategy or tone down the
comments to be something like: [As far as we know, ...].

30. P 14, l 21. Either cite them again or state their size. See 22.

31. P 14, l 24. This is not consistent with earlier comments on the primary
outcome. These could be secondary.

32. P 15, l 8 needs a R.

33. P 15, l 16. Replace [is] by [may be]. Who will decide this?

34. P 20, l 2. If the analyses are completed, where are the results?

35. P 21, l 2. Why was this person not considered to be an author? What are the
person's credentials for doing this?

36. A random sample of 10 Rs was checked for citation accuracy. It appears that
Rs 2, 5, 8, 11, 12, 15 are cited properly.

37. P 22, l 14. R 6 needs a last page of [300].

38. P 22, l 24, R 9 needs a last page correction of [3048].

39. P 23, l 22, should add [(6825)] after [304] to make it easier to find. Does the
correction in BMJ 304(6829):739 matter to the citation?
40. P 23, l 23 to 25. This citation should be deleted since it is already cited as R 11 on the same P.