Reviewer's report

Title: Development of a clinical trial to determine whether watchful waiting is an acceptable alternative to surgical repair for patients with oligosymptomatic incisional hernia

Version: 2 Date: 6 October 2011

Reviewer: Charlie Goldsmith

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This manuscript should consider the following issues in attempt to make this protocol better understood by a reader.

1. P(age) 4, p(aragraph) 2, l(ine) 9. Suggest changing [headed] to [person].

2. P 4, p 4, l 1. Claiming [no prospective trail] without a detailed literature search that is described does not justify this wording. How about something like: [We could find no published data on the natural course of incisional hernias]. And in the next l, words like [never been compared] as also somewhat strong. You may not know of such a comparison and have justified it to your funders and ethics committee; however, the wording should be toned down for publication unless you provide a credible literature search. Also P 12, p 1, l 7 and p 2, l 1.

3. P 5, p 1, l 1. [Incidence] needs a time to be correct. Is this annual?

4. P 5, p 1, l 4. Suggest replacing [significant] by [large]. Save significant for its statistical context.

5. P 5, p 2, l 1. Replace [recent nationwide] by [2009 German]. The date is always relevant while recent it not the same for all readers, and goes out of date with time passage. Also readers come for a variety of countries and may not know if it is German.

6. P 5, p 3, l 1. This would be a good place to define [incarceration] as it is used surgically. When I read it I wondered why surgeons were putting patients in jail! One definition from Webster’s Dictionary is: “abnormal retention or confinement of a body part, specifically: a constriction of the neck of a hernia sac so that the hernial contents become irreducible.”

7. P 5, p 3, l 3. Is this a case of statistical significance? If yes, say so. Also provide a R(eference) to the paper.

8. P 5, p 4, l 3. Keep the number of decimal places the same for an interval, so consider replacing [6] by [6.0] if that number is correct.

9. P 5, p 4, l 5. Suggest dropping [only] as it implies an unstated expectation, unless you want to say whether this is high or low.

11. P 6, p 4, l 5. Replace [ranged] by [varied].


13. P 7, p 2, l 9. Suggest rewriting as [a mean SPS score of 12.0 with a SD of 12.0 and ...] Avoid using [±] between the mean and standard deviation. If you intend the readers to add and subtract these two numbers then do it for them! Also is [0.5] the inferiority margin you used in the sample size calculation? You should provide a reference to this idea, since it is unusual in the surgical trial literature. You should also cite the software used to compute the sample size justification.

14. P 2, p 2, l 11. What is the justification for using a power as low as 80% for an inferiority trial? It is usually put at least 90%. Can you cite a good reference to justify this choice? At least your surgeon investigators should be happy with it, and you could document that.

15. P 2, p 2, l 14. To inflate the sample size for dropouts you need to divide by the compliment as 572/0.9 = 635.5 grown to 636; not multiply by the dropout rate as 572x1.1 = 629.2 grown to 630. This revised number should also be included in your flowchart at the recruitment part. You should consider using the CONSORT guidelines for creating a flowchart for the follow-up of the patients in your trial. Also imputation methods should be considered to handle missing data in the trial.

16. P 7, p 4. This description of what costs are going to be collected needs a description as to the source of the costs, as well as how they will be used in the economic analysis. Whose viewpoint will be used and whether you will be using a disease specific, generic or utility based measure of quality of life with suitable references to the methodology. Is there a health economist on your team?

17. P 7, p 5, l 1, 2 (twice). Insert [statistically] in front of [significance].

18. P 7, p 5. Since you hypothesize that these tests will be for superiority, are they going to done as 2 tailed tests and at the same level of significance since they are clearly secondary? How will multiplicity be handled?


20. P 8, p 1. All of these outcome measures should be documented with references, measurement properties, and interpretation, version numbers and how they have been validated if they have been translated into German if they were not developed in German. Certainly HADS-D and SF-36 were not developed in German. How reliably are these measures collected in the study sites?

21. P 8, p 2, l 1. Insert [relative] between [The] and [frequency].

22. P 8, p 2. How well is this event of acute incarceration measured? Is there
agreement published on this, and are your outcome measurers skilled in doing it? Do you have any data to demonstrate that this is well measured?

23. P 8, p 2, l 5. Insert [also] after the second [is].

24. P 8, p 3. All these numbers are not in the Figure. Consider using the CONSORT format for your trial.

25. P 9, p 1, l 6. Since this system has been validated, is the validation published? Is there a website that describes its properties? Please include this information.

26. P 9, p 1, l 9. Since the study is stratifying by center and hernia size, there is no expansion of the sample size to accommodate these. This reviewer would do so by increasing sample size by 1 for the hernia stratification and 13 for the 14 proposed sites of recruiting to accommodate the loss in degrees of freedom required in your sample size justification. Was it considered? Also a t test is not proper in the analysis since it does not consider these constraints on the randomization. These should be taken into account by adjusting for these features in all the analyses. If you are not choosing to do so provide a reference as to why not.

27. P 9, p 3. Any procedures being left for the surgeon to decide should be recorded to see if they have any impact on the conclusions of the trial. They might be adjusted for in a secondary analysis.


29. P 10, p 2. Define these measures and ideally provide a R as to how they are measured or where they are standardized. Also P 10, p 3.

30. P 10, p 3. This analysis section is not adequate. It needs to document how the analyses will be done and what software will be used to do them. You should also define each analysis set such as ITT and As Treated, providing Rs as well. If there is a statistical analysis plan (SAP), it could be included as an appendix.

31. P 11, p 2, l 3. Include the date of registration.

32. P 11, p 4. The forms could be included as appendices. If they are already published, they could be cited.


34. P 11, p 5, l 54. Since it is now October 2011, has the first patient been randomized? If so, state the date.

35. P 12, p 1, l 4. Replace [significant] by [large].

36. P 12. The authors should consider listing the 14 centers and well as creating a list of all the short forms used in the manuscript. Having them all together can help a reader. One should also not assume that all readers know all short forms. See also Table 12 where many short forms are used, yet not defined.
Trials likes to publish ALL authors. So any Rs that use [et al] should replace them by the rest of the authors. This reviewer took a random a sample so 10 Rs for citation checking. Also this reviewer likes to use issue numbers as they make it easier to find the reference in most journal data bases and libraries if it is needed. Also the last P number just needs to record the digits that change.

37. P 13, R 2. Insert the date all websites were accessed as they may change.

38. P 13, R 3, l 2. Insert [(12)] after [96].


40. P 13, R 7, l 2. Insert [(1)] after [7].

41. P 13, R 9, l 1. Replace [et al] by 3 more authors.

42. P 13, R 11, l 2. Insert [(1)] after [195].

43. P 13, R 12, l 3. Insert [(4)] after [203].

44. P 13, R 14, l 2. Insert [(3)] after [12].


46. P 13, R 17, l 3. Insert [(5)] after [196].