Reviewer's report

Title: Pancreatogastrostomy versus pancreateojejunostomy for RECONstruction after partial PANCreatoduodenectomy - A randomized controlled trial (RECOPANC)

Version: 1 Date: 16 November 2011

Reviewer: Charlie Goldsmith

Reviewer's report:

The following comments are offered to improve this protocol. The pages were numbered from 1 to 17.

1. P(age) 2, p(aragraph) 1, l(ine) 6. Replace [failed to ] by [did not]. Failed to implies it should have. The truth may be that there is no detectable difference. Also P 3, p 3, l 3.

2. P 2, p 3, l 1. Replace [significant] by [clinically important]. Reserve significant for its statistical context.

3. P 2, p 4, l 1. Include the data of registration as well as the date the first patient was randomized, if that has happened.

4. P 3, p 1, l 5 and 6. Replace [one hundred years ago] by the actual date and R(eference) it. This phrase loses it accuracy with time.

5. P 3, p 1, l 9. Replace [incidence] by [rates]. Incidence is the rate of conversion from non disease to disease over a specific time. Time has not been stated. Also replace [range] by [interval]. A range is the length of an interval and is a single number.

6. P 3, p 3, l 2. It is unclear whether there were one or two meta analyses? If the latter, make [metaanalysis] into [metaanalyses].

7. P 3, p 3, l 3 and 5. Add an [s] to [RCT] to read [RCTs]. This short form is not in the list on P 10.


9. P 3, p 4, l 3. Delete [In order] and capitalize [To]. The words are redundant in English. Also P 4, p 1, l 7. Also P 4, p 3, l 1. Also P 5, p 4, l 1. Also P 6, p 2, l 6. Also P 6, p 4, l 8.

10. P 4, p 1, l 7. Replace [etc.] by the list of other variations in technique. These should also be listed in the CRFs to make sure there are no hidden flaws related to these choices. This could then be studied as exploratory for a future trial.

11. P 4, p 3, l 3. This needs a better R.

12. P 4, p 5. Is there evidence that the scoring of the B or C grades are done reliably? Are there plans to train the scorers? How reliable will they need to be after training to use them in the trial? Presumably they will be different person at each center.
13. P 5, p 1, l 1 Delete [in order]. Also P 5, p 2, l 2.
14. P 5, p 2, l 56. Provide Rs for these tools. Also the scoring and interpretation should be included along with their measurement properties.
15. P 5, p 2, l 10. Replace [etc.] by the list of things being measured, ideally with Rs.
16. P 6, p 2, l 2. This suggested difference of 10% looks large to this reviewer. Why is this the Minimum Clinically Important Difference (MCID)?
17. P 6, p 2, l 4. What software was used to get the 153 per group? This reviewer used PASSS 11 and also got 153. With a drop out rate of 15% this justifies the 360. The 158 from the interim analysis is not reflected in the Flow chart on P 14. This sample size justification does not take into account the stratification and blocking being suggested. While centers sometimes have an effect, this should be inflated by 15 to accommodate the 14 centers; the blocking will not likely have an effect on the analysis being proposed. On l 5 and 6, the Chi-square should be replaced by the logistic regression being proposed in the analysis section.
18. P 6, p 2, l 11. Delete [10-] as the upper bound is what is need to inflate the sample size for dropouts.
20. P 6, p 3. Put in a R for the software being used for the analysis.
21. P 6, p 3, l 7 and 8. This pre specified subgroup analysis should state exactly how the conclusion will be justified. Subgroups are usually underpowered in this type of study. Is the MCID the same here?
22. P 6, p 4, l 8 and 9. How will the missingness be handled if they do not give consent?
24. P 7, p 1, l 5 twice. Delete [and/] as [or] logically includes [and].
25. P 7, p 4. What software will be used to decode the eCRFs and the do the data management?
26. P 8, p 1, l 11 How many surgeons?
27. P 8, p 3. Provide Rs for these documents.
28. P 9, p 2, l 1. Replace [failed to support] by [not supported].
29. P 10. Add [RCT] to the list.
30. P 14, last two rows of boxes contain [See 3.7] and should likely be deleted. This flow chart should follow the CONSORT guidelines for reporting.

Trials likes to include all authors. So the Rs that have [et al] should include ALL the authors, ie, R 17 is one. This reviewer also likes to use the issue numbers as well, as they make finding the R easier than without them. A random sample of 10 Rs was checked for citation accuracy. All the Rs should be in English. If they are in another language the convention is to translate the title into English, put the title in [square brackets] and then include the language at the end of the R in (round brackets); ie, Rs 19 and 21 which appear to be in German. Journal titles
could use Index Medicus short forms and capitalize the terms.


32. P 15, R 4, l 3. Insert [(3)] after [245].

33. P 15, R 7, l 3. Insert [(12)] after [29].

34. P 15, R 10, l 3. Insert [(4)] after [13].

35. P 15, R 11, l 4. Insert [(4)] after [222].

36. P 15, R 12, l 4. Insert [(6)] after [189].


39. P 15, R 17, l 2. Replace [et al] by [Yeo CJ, Buchler MW] and on l 2 of P 16, insert [(5)] after [142].

40. P 16, R 19 could not be found to be verified. It should be translated into English.

41. P 16, R 20, l 2. Insert [(4)] after [50].

42. P 16, R 21 should be translated into English. It could not be found.