Reviewer's report

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

Version: 2 Date: 19 December 2011

Reviewer: Charlie Goldsmith

Reviewer's report:

While the answers to the reviewer comments from the first review look sensible apart from the sample size expansion due to centers, the revised text looks as if nobody has read it over for sensibility. This should have been done. There are now a new set of issues that should be considered by the authors.

The pages in the revised protocol have been numbered from 1 to 18.

1. P(age) 2, p(aragraph) 1, l(ine) 6. Delete [have].
2. P 2, p 3, l 1. Replace [significant] by [clinically important].
3. P 4, p 5, l 17. Given that different centers may have different standards for determining serum amylase activity, and this could make the 3 times upper limit of normal different by center, it is more important to stratify by center and hence inflate the sample size by the number of centers to accommodate this adjustment in the analysis.
4. P 5, p 2, l 1. Replace [To] by [to] since they are not at the start of a sentence. Also P 5, p 3, l 3.
5. P 5, p 5, l 12. Rewrite as [To achieve …].
6. P 6, p 2, l 6 to 8. Since this reviewer does not think this is a universal fact, the authors should provide a reference to the veracity of this issue. It impacts the sample size calculation and also the analysis.
7. P 6, p 4, l 3. Replace [population] by [patients]. No study contains a population. Also provide a reference to the definition of ITT that you are using. Many surgical studies do not use the proper definition of this term.
8. P 6, p 4, l 4. Apart from the 14 plus centers, how many levels of age, levels of surgical experience, and texture of pancreatic tissue will be used in the analysis. As long as there are no interactions of these adjustments with treatment, the levels should be used to expand the sample size to accommodate these features.
9. P 6, l 4, l 9. How many of the patients are expected to have a soft pancreas? Is it possible to stratify on this fact prior to randomization? This ensures close balance in each level of this factor. This could have an impact on the subgroup analysis and whether it will be statistically significant. It is important that the interaction between pancreatic softness and treatment be also tested for to provide a valid subgroup analysis. The authors should provide a reference to the
principles they are using for this subgroup analysis.

11. P 7, p 3, l 7. Delete [and/].
12. P 7, p 5, l 3. Provide references to these guidelines.
13. P 7, p 6, l 4. Is there a reference or website that describes the features of this software? If so, provide it.
15. P 8, p 3, l 6. Suggest deleting [appropriate]. This will not be known until after if is done!
16. P 10. Both [EDC] and [ICAr] are missing from this list.
17. P 16, references 20 and 23. The [square brackets] should be around the English translations of the titles and the [German titles] in square brackets as well as German titles for each of these references should be deleted.