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: 3 Date: 21 November 2011

Reviewer: Charlie Goldsmith

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Here are some issues for the appendices that the authors should consider.

Case Report Form appendix

1. It should be noted that all these forms appear to be in German. This should be noted before a reader opens them thinking they will be in English.

2. It is interesting that the date format on ALL the forms is in the format: tt.mm.jjjj while at the footer of ALL the pages it is yyyy-mm-dd as 2011-08-26. The authors should consider making this latter one the standard format.

Statistical Analysis appendix.

The pages were numbered 1 and 2.

In general, this analysis plan would not allow for a reproducible analysis to be conducted and should be written with this in mind. For example there is no mention of the stratification mentioned in the protocol, and the software for the data bases and analyses are not documented. Here are some additional issues that should be considered.

   1. P(age) 1, p(aragraph) 2, l(ine) 1. It is no longer adequate to use the [±] between two numbers that are not defined. So why not rewrite the text as […] activities {mean (SD)} 10.3(14.9) in the …]. On the next l rewrite as [10.4(14.9)].

   2. P 1, p 2, l 6. Rewrite as [(95% confidence interval: -1.2 to 1.5)].

   3. P 1, p 2, l 7. Rewrite as [, SPS scores were 12.0(12.0) and …].

   4. P 1, p 5, l 5. Rewrite as [n = 2 x 286 = 572.]. This is a sample and not a population. Also later in the l, rewrite as [n = 636].

   5. P 1, p 5, l 7. Reference the source of the software.

   6. P 2, p 1, l 1. Replace [population] by [patients]. This will not be a population. Also insert after [(ITT)] the words [, ie, all patients randomized]. There are many in surgery who do not know this definition.


   8. P 2, after p 2. This would be a good [place to outline the data management and a typical model of the proposed analyses as no mention has been made]
about stratification as part of the initial models. Document the software as well.
9. P 2, p 3. This should include how you will interpret the subgroup analyses as they will not likely have adequate power to detect differences between the arms. Also do you plan to satisfy the 3 issues of a credible subgroup analysis: a prior reference and statement as to what factor(s) will be looked at, significant interaction between the subgroups and treatment, and significance in some subgroups but not others. These ideas used should also be referenced.