Reviewer’s report

Title: Titanium vs absorbable tacks comparative study (T.A.C.S. trial) during laparoscopic repair of ventral and incisional hernias: study protocol for multicenter non-inferiority randomized controlled trial

Version: 1 Date: 6 April 2015

Reviewer: Jane Blazeby

Reviewer’s report:

It is interesting to read this trial protocol. I have a number of concerns about the description of the design which require clarification. In addition it would benefit from work on the language and writing to improve readability

Major issues

1. The rationale for the study is confusing and I think it needs to critique the current evidence in terms of descriptors of previous studies and their design

2. The primary end point is unclear in the abstract which states a hypothesis but no clear focus this this – elsewhere it appears that the primary endpoint is recurrence rates but at three time points - this requires clarification

3. There is a need to avoid the use of ‘double concealment’ – because of confusion of this terminology - although it is noted that it is possible to blind patients and outcome assessors which should reduce bias in this trial

4. The discussion in the abstract repeats the aim and it appears that this study is aiming to ‘demonstrate’ something, rather than test a hypothesis - therefore I have concerns about bias

5. It is unclear whether the patient will be expected to provide informed consent for the research and randomisation or whether this protocol describes simple informed consent used for clinical practise.

6. It is unclear how allocation concealment will be maintained, I am not sure what restricted access for each unit means?

7. Methods to analyse videos on the surgeons are not described

8. I do not understand the assumptions around the sample size calculation -

Level of interest: An article of limited interest

Quality of written English: Not suitable for publication unless extensively edited

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.
Declaration of competing interests:

I declare that I have no competing interests