Reviewer's report

**Title:** Efficacy and Safety of Active Negative Pressure Peritoneal Therapy for Reducing the Systemic Inflammatory Response After Damage Control Laparotomy for Severe Intra-abdominal Sepsis or Injury: Study Protocol for a Randomized Controlled Trial

**Version:** 3  **Date:** 9 March 2013

**Reviewer:** Olaf Bakker

**Reviewer's report:**

Major Compulsory Revisions

1. **Introduction:**
   Please refer to clinical studies in which IL-6 has proven to be an accurate predictor of outcome? Now, I believe only animal studies are mentioned.

2. **Methods, overview:**
   Please indicate whether this is a superiority trial.

3. **Intervention and comparator choice rationale:**
   Is there any evidenced that Abthera promotes “active, equally distributed vacuum pressures”. If so, please refer to this evidence.

4. **Study endpoints:**
   Primary endpoint:
   I would suggest to blind the investigator performing the laboratory tests for treatment strategy/randomization.

5. **Sample size:**
   Please include data on the feasibility of the sample size. How many patients are potentially eligible in your hospital for example each year?
   Please mention whether this is a superiority trial.

6. **Statistical Analyses, last paragraph:**
   I do not fully agree with the explanation to not too correct for multiple statistical tests. When using an essay with many cytokine outcomes the chance of finding a significant difference caused by multiple testing is substantial. In my opinion a correction is necessary. Although the findings will be explanatory, significant results in favour of Abthera will be presented as such. Please comment.

7. **Discussion:**
   Please also address that planned relaparotomy is not the evidence based strategy of choice for secondary peritonitis (see RELAP trial, van Ruler et al.)
8. Table 2.
If this is a standard essay it is not necessary to show all outcomes of measurements. It is also sufficient to refer to the test and manufacturers.

9. Figure 1.
Please adhere to the CONSORT guidelines to show the flow of participants, including lost to follow-up etc.

10. Additional comment:
Would it be possible to show a picture or drawing of the different closure devices? That would be insightful for readers.

Minor Essential Revisions

11. Introduction, second paragraph: What is mechanical hemorrhage?

**Level of interest:** An article of importance in its field

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**
I have no competing interest.