Reviewer's report

Title: A multicenter randomized controlled trial evaluating the effect of small stitches on the incidence of incisional hernia in midline incisions (STITCH trial, NCT01132209)

Version: 1 Date: 22 February 2011

Reviewer: Heinz Zimmermann

Reviewer's report:

The manuscript is a surgical study protocol evaluating the effect of small stitches on the incidence of incisional hernia in midline incisions.

Major Compulsory Revisions

The protocol for this randomized controlled trial does not follow the CONSORT guidelines (http://www.biomedcentral.com/1471-2288/1/2) in all aspects:

a) The trial is not a double-blinded trial in all aspects: The surgeons and nurses know the technique used. However patients, investigators and radiologists are blinded.

b) The randomization process is not given in detail. Allocation concealment is missing. Implementation is not given in detail (see CONSORT guidelines).

c) Objective: Primary and secondary endpoints should be given here too and not only in outcome parameters.

d) Objective: Give details to the meaning of „significant reduction of costs“.

e) Methods: There are 10 surgical units and only one gynaecological unit: do you not expect a bias?

f) Trial design: It is not clear, if the surgeons and residents performing the operations are performing the evaluation too.

g) Trial design/Interventions: How is he instruction of the surgeons, residents, nurses performed?

h) Trial design/Outcome parameters: What are the specific criteria of the postoperative ultrasonography for incisional hernia?

i) Trial design: What are the definitions used for wound infection?

j) Participants: Emergency laparatomies are only included if the patient is able to sign the informed consent. This may give rise to bias as probably sicker patients are not able to sign.

k) Outcome parameters: what are the criteria for a clinically detected incisional hernia?

l) Statistical analysis: Is there a interim analysis planned?

m) Statistical analysis: How will the predefined, well established predictors recorded?
n) Monitoring: Who is he sponsor?
o) According to the GCP guidelines, patients should be enrolled in only one trial.
p) Discussion: See above: How is the standardisation of the two techniques in the many residents and surgeons performing the wound closure performed?

Minor Essential Revisions
The trial is registered and the link should given as appropriate:
http://clinicaltrials.gov/ct2/show/NCT01132209

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

**Quality of written English:** Acceptable

**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