Author's response to reviews

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

Authors:

Joris J Harlaar (joris.harlaar@gmail.com)
Eva B Deerenberg (e.deerenberg@erasmusmc.nl)
Gabrielle H van Ramshorst (g.vanramshorst@erasmusmc.nl)
Harold e Lont (hlont@ssyz.nl)
Ed CMH van der Borst (e.vd.borst@elisabeth.nl)
Willem R Schouten (w.r.schouten@erasmusmc.nl)
Joos Heisterkamp (j.heisterkamp@elisabeth.nl)
H C van Doorn (h.vandoorn@erasmusmc.nl)
Frits Berends (FBerends@alysis.nl)
Hein BAC Stockmann (stockmann@kg.nl)
Wietse W Vrijland (w.vrijland@sfg.nl)
Ester Consten (ecj.consten@meandermc.nl)
Reyer T Ottow (rever.ottow@ghz.nl)
Huib A Cense (hcense@rkz.nl)
Peter MNYH Go (go@antonius.net)
John J Hermans (j.j.hermans@erasmusmc.nl)
Ewout Steyerberg (E.Steyerberg@erasmusmc.nl)
Johan F Lange (j.lange@erasasmus.nl)

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Author's response to reviews: see over
Dear reviewer,

On behalf of the REPAIR research group of Rotterdam, the Netherlands, I am pleased to answer the questions in your comments on our manuscript: ‘A multicenter randomized controlled trial evaluating the effect of small stitches on the incidence of incisional hernia in midline incisions (STITCH trial, NCT01132209)’

In general, we would like to thank for your comments, which have led to a better and more complete protocol. Please see our revisions in the revised protocol and answers below:

**Sample size.**

How has been computed the sample size?. By using different open access software (Epidat 3.1, for instance), assuming the exponential model (as usual) and, under the requirement described in the Sample size calculation section, the number of required patients is 288 per group (the 10% of follow-up lost is already included). Other open access software lead to the same number.

The sample size is adjusted; our statistician explained that he used fixed endpoints. Now we have the mandatory 288 patients per group.

**Statistical analysis.**

In the variable descriptions must be included mean and standard deviation. In special, when parametric tests are not discarded (T-test is considered in the guidelines). In addition, explain where you are going to used each one is advisable. As usual, it would be enough with writing: *when normality assumption were not rejected (by using Kolmogorov-Smirnov with Lilliefors correction test or Shapiro-Wilks)*.

We agree with the reviewer. This is adjusted in the revised manuscript.

In addition, in the statistical guideline, is not include how the longitudinal variables are going to be analyzed. Quality of life will be assessed at four different moments. Will be this evolution analyzed? How?. I think the method used in these analysis must be reflected in the protocol (probably some of the following tests will be used: T-test paired, repeated measures, Friedman, McNemar).

We agree with the reviewer. This is adjusted in the revised manuscript.

Finally, How have been selected the adjustment covariates?. Perhaps some usual epidemiological variables such that centre and gender must also be included.

At final of the Sample size calculation and in the Statistical analysis, you say that the power of the test for treatment effect increases when you adjustment for covariates. However, this is not necessarily true. When you adjust by covariates, you detect better the isolated effects of your treatment, however this fact does not ensure a increment of the statistical power (obviously, depending on the covariate effects). Moreover, you must estimate more parameters and the same effect (OR/HR) could be no significant. I think that is better removing both sentence and only remark that and adjustment by covariates will be made.

We agree with the reviewer. This is adjusted in the revised manuscript.

**Discretionary Revisions**

In Economic evaluation: *Bootstrapping techniques will be used to increase power.* This sentence is extremely vague. What sort of bootstrapping will be used and where? (naïve, smoothed, bayes...) or perhaps only the Monte Carlo method?. The tests which appear in the Statistical analysis section, could be compute in the exact form (in particular, the t-test is an
exact distribution). If you have computed the sample sizes via bootstrapping, what model has been assumed?
We agree with the reviewer. This is adjusted in the revised manuscript.

Looking forward to your reaction and hopefully a future acceptance in this reliable surgical journal.

On behalf of professor Lange and professor Steyerberg,

Best Regards,

Joris Harlaar