Reviewer's report

Title: A prospective double-blind multi-centre trial: Laparoscopic versus open elective sigmoid resection in patients with symptomatic diverticulitis (Sigma-trial)

Version: Date: 28 May 2007

Reviewer: Markus K. Diener

Reviewer's report:

General
The study protocol publication of Klarenbeek et al. outlines the design of a randomized controlled multi-center trial evaluating laparoscopic versus conventional sigmoid resection for diverticulitis.

Taking into account the objective, primary endpoint and methods of conducting and analysing the trial, we feel that SIGMA-Trial is well prepared for an adequate test of the hypothesis. The trial protocol is concise and well written.

However, there a couple of issues that might need revision, which are listed in the following:

1. Abstract: The aim / goal of the trial is not precisely formulated in the abstract. It would be useful to include one sentence at the end of the background section like “The sigma trial is designed to evaluate the effectiveness of lap. versus conv…
2. Abstract: How is postoperative morbidity defined? When is it measured?
3. Abstract /Discussion: 2nd line “to define the role of laparoscopic treatment” – “to define the role of lap sigmoid resection” would be more straightforward.
4. Methods & Design / Endpoints: Again, how is the primary endpoint defined in detail and when is it measured? The second sentence of this paragraph is confusing, something missing? Please keep in mind that the primary endpoint is the very basic and essential item of the trial. So it cannot be specified and defined enough (e.g. definitions of clinical outcome parameter such as anastomotic leakage, abscess, wound infection etc. should be defined).
5. Methods & Design /Participating surgeons and clinics: could you give a reference for the statement regarding the learning curve effect?
6. Methods & Design /Randomization: Postoperative dressing refers to blinding not to randomization (might be confusing in this paragraph). Moreover, how long will the opaque dressing be maintained? How will it be changed? Please specify, if possible.
7. Methods & Design: The Protocol publication would potentially benefit from specification of the study hypothesis (H0 / H1 hypothesis). Also, statistical methods of analysis should be defined such as per-protocol versus ITT Analysis, planned interims analysis etc.
8. Specification of surgical technique: how will the anastomosis in the open group be performed? However, the manual for the surgical technique is very well done.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Discretionary Revisions (which the author can choose to ignore)

What next?: Accept after minor essential revisions
Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I have no competing interests

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