Author’s response to reviews

Title: Treatment of Acute Diverticulitis Laparoscopic Lavage vs. Resection (DILALA) A Randomised Trial

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Answers to questions/queries from reviewer:

a. **Question RE block randomization**: The block size for randomization is ten. Each envelope is closed, the envelopes in each block are numbered from 1-10 and should be used in that order. The allotment within the block is also random. Theoretically the group assignment in the last one or two envelopes could be anticipated, if the including/operating surgeon is aware of the assignment for the earlier ones in that block. However, in our experience this would be highly unlikely. Perforated diverticulitis with peritonitis is an emergency situation, and in hospitals in Sweden and Denmark the decision to operate as well as the operation is performed by the staff surgeon on call, thus any one of the surgeons may be involved. Changes in the manuscript to clarify procedures are marked. A section clarifying this has been inserted page 5, “RANDOMISATION AND SURGICAL PROCEDURES”.

b. **Question on objective outcome assessment**: A blinded trial is not possible, as half of the patients have a colostomy at least for several months. Thus neither the patient nor the surgeon/nurses can be blinded. The use of structured CRFs, with very detailed questions about complications, side effects, need for re-operations/re-admittance for the surgeon at each Follow up (FU), is one way to meet this problem. The monitoring visits are another way to address the problem. Focus will be on information in patient charts and compare that to the information in the CRFs at FUs. Further all patients answer questionnaires at each time point for FU. A clarification of this point has been inserted page 5, “FOLLOW-UP”.

c. **Question RE exclusions, intention to treat**: Inclusion i.e. informed consent is before surgery, but randomization is after the initial diagnostic laparoscopy i.e. during surgery. If the laparoscopy shows a diverticulitis Hinchey III, (peritonitis with pus in the abdominal cavity and a diverticulitis), the patient is randomized by taking the next envelope from the block of ten. Patients diagnosed with a colon cancer, appendicitis or perforated stomach ulcer at the diagnostic laparoscopy are not randomized as they do not fulfill criteria for randomization. Patients, who are randomized as Hinchey III, but are found to have a perforated colonic cancer on pathology examination of the surgical specimen, are excluded, in accordance with the protocol. Intention to treat will be followed at analysis, a patient with Hinchey III diverticulitis randomized to laparoscopic lavage but converted to open surgery and Hartmann’s procedure will be analysed in the laparoscopic lavage group. Our power calculation gave the figure 32 + 32 and we have permission by the ethical committee to randomize 40 +40 patients. Changes in the manuscript to clarify procedures are marked. These questions have led to changes to clarify “inclusion”, “randomization” and “exclusions”, page 4 “INCLUSION CRITERIA”, “RANDOMISATION CRITERIA”, “EXCLUDED FROM RANDOMIZATION”, “EXCLUDED AFTER RANDOMIZATION”.

d. The spelling/wording suggestions have been followed and are marked.