Reviewer's report

Title: A prospective, double-blind, multi center, randomized clinical study to compare the efficacy and safety of Ertapenem 3 days versus Ampicillin-Sulbactam 3 days in the treatment of localized community acquired intra-abdominal infections. (T.E.A. Study: Three days Ertapenem vs three days Ampicillin-Sulbactam)

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Reviewer: Greger Lindberg

Reviewer's report:

This protocol describes a study aimed at comparing the failure rates of two different antibiotics for acute intra-abdominal infections. Both antibiotics are intended to be given for a shorter than normal period of 3 days. It is important to search evidence in favour of reducing the use of antibiotics. However, it is difficult to find sponsors for this type of studies, since they may contradict the aims of pharmaceutical companies.

The authors wish to compare two 3-day regimens comprising in one arm ertapenem and in the other arm the combination of ampicillin and sulbactam. The study size builds on an assumed 3-fold better efficacy of ertapenem. Although the appropriate research ethics body has already approved the study, the current description raises a number of questions that need to be answered:

Major Compulsory Revisions

1. The title of the manuscript is misleading in two ways. Firstly, this is not a blinded study at all and certainly not at double-blind study. Both the patient and the doctor will know the type of treatment. Even though some of the evaluation will be done by a third party presumably blinded for treatment allocation, I would suspect that the case review will reveal also the treatment allocation. Secondly, the title says that this is a multi-centre trial but although two of the authors come from other hospitals (Riuniti Hospital, Bergamo and Maggiore Hospital, Bologna) the protocol only mentions patients from St. Orsola-Malpighi University Hospital. The latter indicates a single-centre study. Please change the title.

2. The primary endpoint is the failure rate. However, the protocol lacks a firm description of "failure" as well as the timing of its evaluation. In the paragraph Data Collection both "failure" and "late failure" are mentioned. The definition of the primary endpoint is crucial to this study. Hence it needs a clear definition. Please include a clear definition of the primary endpoint. Please also state the secondary endpoints under a separate heading (Secondary endpoints).

3. The sample size was determined from the hypothesis that treatment with ertapenem should give no more than 10% failures. This is reasonable given the results from the study by Basoli et al. (ref #6). However, the basis for assuming
that ampicillin-sulbactam would lead to at least 30% failures is not stated. Please clarify how the figure 30% was arrived at since this is crucial for the size (n=142) of the study.

Minor Essential Revisions

4. There are some peculiarities regarding the order of events that either require re-writing or explanation:

4.1 In Randomization the text reads "if the patient fulfils the inclusion criteria the responsible surgeon will disclose the envelope and accordingly to the protocol the patient will sign an informed consent". I don't understand what the authors mean by "disclose the envelope" and in any case this should not be done before obtaining informed consent. Hence, the order should be first to establish if a patient fulfils inclusion criteria and no exclusion criteria, secondly to inform the patient about the study, thirdly to obtain informed consent, and fourthly to randomize.

4.2 In the paragraph Informed Consent or Information Sheet the text reads: "the patient will receive all the information about the study protocol, the confidential nature of personal data and will fill up a questionnaire before signing or refuse." This is an incorrect order of events since the patient should not be asked to fill out a questionnaire before having consented to participation. Hence the order should be information – consent – questionnaire.

5. The manuscript needs a thorough linguistic revision. There are numerous syntax errors, inappropriate use of definite article, and past tense when future tense should be used.

Level of interest: An article of importance in its field

Quality of written English: Not suitable for publication unless extensively edited

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

Declaration of competing interests:

I declare that I have no competing interests