Reviewer’s report

Title: “Is dangling of the lower leg after a free flap reconstruction necessary? A study protocol for a large multicenter randomized controlled study.”

Version: 0 Date: 26 Jul 2019

Reviewer: Patrick Haubruck

Reviewer's report:

Summary:
The authors of the manuscript present the study protocol for a RCT investigating the clinical effectiveness of a dangling protocol after free cutaneous flap transfer. The authors plan to conduct a multi-center study to prove non-inferiority of dangling compared to non-dangling. A total of 130 patients over two years will be included. In general, the study purpose is of interest and a well-designed RCT will be able to provide reliable evidence to that question. The manuscript was prepared well and the study well thought off. That being said, I do have some concerns and believe that the overall quality of the manuscript and study can be improved by addressing them.

Concerns:
1. Please revise the title of the study and point out that this is the study protocol and not the results of the actual study itself. At present the title is misleading.
2. Please revise the introduction in the same regard and point out that this is just the protocol.
3. Please revise the first sentence of objectives and make it more precise. At present the sentence is too long and confusing.
4. What is the standard of care in the participating centres at the moment? If the standard of care is the non-dangling protocol the authors should mention that, if the standard of care the authors should mention that as well. Furthermore, if the standard of care is something entirely different I wonder why dangling wasn't compared to the standard of care.
5. Please provide some parameters when the study will be terminated due to adverse events. This should be mentions in the method section.
6. At present the discussion is very short. I believe it would help if the authors discuss the potential benefits that can come from doing the study and compare the proposed study design with the other studies that were conducted regarding this question.
7. The authors designed the study as a non-inferiority trial. However, I wonder, if both treatments are equivalent, what are possible reasons that would lead to actually implement a dangling protocol. What is the benefit of a dangling protocol if the study shows that both treatments are comparable? I think that should be briefly explained in the discussion. In particular, if the hypothesis is confirmed, what will be the clinical impact of the study.
8. Regarding the PCOT measurement, how many patients are needed to achieve statistical relevant results? If I understand correctly only once center will perform these measurement. Are enough patients expected to be enrolled in this one center? What is the necessary sample size? If only a handful of patients are expected to get this measurement and feasibility of the statistical analysis
is questionable I believe it is unethical to do these measurements. Especially because they are the only invasive measurements. Please explain and revise manuscript accordingly.

Level of interest
Please indicate how interesting you found the manuscript:

An article of importance in its field

Quality of written English
Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

Quality of figures
All images and figures within the manuscript should be genuine i.e. without evidence of manipulation. No specific feature within an image may be enhanced, obscured, moved, removed, or introduced. If you have concerns about the veracity of the figures you should choose the first option below.

Statistical review
Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.

Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

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Were you mentored through this peer review?

No