Reviewer’s report

Title: Surgical offloading procedures for diabetic foot ulcers compared to best non-surgical treatment: A study protocol for a randomized controlled trial

Version: 0 Date: 03 Nov 2017

Reviewer: Jaap van Netten

Reviewer's report:

The protocol has been markedly improved. I thank the authors for their changes and clarification.

Some remarks:

My main struggle with the protocol is still the primary outcome measure and the groups that are being compared. I understand this much better now, and I can follow most of the logic from the authors. Please correct me if I'm wrong, but from reading your power calculations it seems that your endpoint ("failure") is a composite of initial plus recurrent failure. Initial failure would be "not healed in 12 weeks", recurrent failure would be "recurrent ulcer in 2 years follow up".

If a participant has initial failure (i.e. no healing within 12 weeks), does this mean an endpoint is reached and the trial stops for this participant?

If that is the case, I begin to follow the protocol. And I like the authors' logic. However, this needs to be better described. So in short, this is my understanding of what the authors are doing:

- Primary outcome measure: composite endpoint of initial failure (not healed in 12 weeks) + recurrent failure (recurrent ulcer during follow-up)
- Participants in group 1 are followed until initial failure or recurrent failure
- Participants in group 2a are followed until initial failure or recurrent failure
- Participants in group 2b will cross-over to group 1 (surgery) after 6 weeks, and will then be followed similar to participants in group 1
- Power calculations are based on 20% failure in group 1 and 60% failure in group 2. [Note: the manuscript says 50% for group 2, but this should be 60%, since they describe 10% initial failure in this group, and 50% recurrence]
My main question is: are participants in group 2b who cross-over from that moment on analysed as participant from group 1? Or will they only be used for subsequent analyses?

This is essential to the trial and needs to be explained so that it is clear without any doubt what will be analyzed and how.

Some minor additional points:

- Do you have a website showing the trial registry? I tried to google it, but I couldn't find evidence of registration of the trial.

- If possible, add in-device plantar pressure measurements, especially in the preventative footwear. This may explain ulcerations, and should come additionally to the barefoot plantar pressure measurements

- Adherence: the orthotimer is a small sensor that can be used for objective adherence assessment. I would encourage the authors to try to add this (or a similar) sensor to the RCT, to replace the subjective adherence questionnaires

- Adherence to post-op shoes (and its assessment) is not described, please add

- Various abbreviations are not spelled out on first use (e.g. IP, CBC)

- Rational should be RationalE (page 10 "Randomization")

- First sentence of the discussion (while preventive[…] DFU prevention): please add reference to back this statement

- Discussion: "[…] have signed informed consent for surgery". This is not correct. Your participants sign informed consent to be randomized to either surgery or conservative treatment. They have also signed informed consent that they understand that this mean they cannot choose which one they will have, and they may not necessarily undergo surgery.

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