Reviewer’s report

Title: Self-expanding nitinol stents of high vs. low chronic outward force in de-novo femoropoplitical occlusive arterial lesions (BIOFLEX-COF trial): study protocol for a randomized controlled trial

Version: 0 Date: 12 Sep 2017

Reviewer: Pirathiv Kugathasan

Reviewer’s report:

"Lastly, there exists not a single randomized study comparing primary nitinol 56 stenting versus drug-covered balloon angioplasty to this day and a historic comparison of study collectives shows similar results."

- Please rephrase sentence

- The last part of the sentence does not make any sense. If you refer to results from other studies, please insert reference.

Why is this "objective" section written after the initiation of methods? It should be before methods. Because now it seems that objectives are a part of methods section.

Symptom driven angiography is reported as your secondary endpoint in your flowchart (figure 3), however not mentioned in the description of methods. Please be clear about your primary and secondary endpoints/objectives.

The Rutherford Classification and Walking impairment questionnaire (WIQ) are mentioned without explaining the reason to be included. Please be precise regarding this part of description.

Your randomization procedure should be more precise, the description is lacking.

In the section of "follow up", you refer to figure 3 about details of clinical assessment, however that is not true. No specific information are gathered from figure 3. Please change your figure 3 if you want to refer to it.

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

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