Reviewer’s report

Title: Polidocanol versus hypertonic glucose for sclerotherapy treatment of reticular veins of the lower limbs: study protocol for a randomized controlled trial

Version: 4 Date: 5 June 2014

Reviewer: George Thanassoulis

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Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)

1. The major issue with this protocol is the inadequate description of the outcomes. The authors state that "efficacy" will be the primary outcome but provide no details as how this will be defined. There are similar issues with some of the secondary outcomes. Please add a section to the protocol entitled "Outcomes" and clearly delineate what the primary outcome will be and how it will be measured using with sufficient detail to ensure that this study could be reproduced by another group. In particular, the scoring of excellent, very good, good, bad, very bad needs further clarification. How are these judgements made? There are also 2 ways to define efficacy: a subjective "eyeball" score and a sophisticated image analysis technique. Which is the primary outcome? Please also clarify how the image analysis will be scored to produce a measurable outcome.

2. Please also clarify the treatment intervention. How many reticular veins can be treated in the study treatment session? Although the authors state that 30 injections are allowed, is the size of the area treated standardized? Could treatments over large areas have different efficacy than over smaller defined areas?

3. The authors state: "The treated area will be photographed with a D7000 Nikon high definition camera in a standard predefined patient position (patient standing on a platform, laterally, 1.5 m away from the camera)." Will this be before or after the initial treatment? Isn't a baseline pre-treatment picture needed? The way this is written implies that the picture will be taken after the treatment.

4. Without a clearer description of the outcomes, the adequacy of the sample size cannot be judged.

Minor issues not for publication

The writing needs to be improved and I suggest the authors consider further editing of their manuscript to improve the language and style. I have highlighted a
few areas (not an exhaustive list) that should be addressed:

1. It’s also common seen in dermatologic and vascular surgery practice with various symptoms. Even so it is still poorly understood.[4] The sclerotherapy is considered to be the treatment of choice for many patients and is performed by physicians because it is a simple, minimally invasive procedure which avoids surgery.[5, 6]

Please rephrase above. Please also avoid contractions (i.e. it’s).

2. The diluents may be distilled water, air, or a range of glucose concentrations.

There is a word missing

3. This is especially true when polidocanol if used in unusual concentrations and volumes which increases the risk of other complications such as chest pain, cough, scotoma, and gas embolization. Moreover, to date, it’s not discarded that it may cause anaphylaxis.[14-16].

If should be replaced by is. There are several contractions that must be revised.

4. This study is a trial is a single-center, prospective, randomized, triple-blind trial.

Please rephrase

5. Patients will be obtained from a convenience sample generated from the patients’ spontaneous desire to treat mild varicose veins

"Obtained" should be "recruited"

6. These patients will be pooled in an electronic database and, later on, they will be invited by phone call to attend an outpatient evaluation.

Please clarify. I don’t think "pooled" is the right term.

7. With the end of the treatments and visits for clinical evaluation, the collected data will be plotted in an excel spreadsheet...

Plotted is not the correct term