Reviewer's report

Title: Acupuncture Treatment for Carotid Atherosclerotic Plaques: Study Protocol for a Pilot Randomized, Single Blinded, Controlled Clinical Trial

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Reviewer: Maryam Golmohammadi

Reviewer's report:

Peer review on manuscript
"Acupuncture treatment for carotid atherosclerotic plaques: protocol for a randomized, blind clinical trial"

26th May, 2020
This is an interesting study protocol that provide knowledge about safety and efficacy of acupuncture treatment for carotid atherosclerotic plaques. In brief, in order to achieve this goal, the authors are conducting a randomized clinical trial of 105 cervical atherosclerotic plaque patients into three groups (TA, SA, and MC) that will be allocated at a 1:1:1 ratio. Participants in the TA group (Acupuncture group) will receive acupuncture related intervention by skilled acupuncturist on the location of acupoints called Neiguan (PC6), Yanglingquan (GB34), Renying (ST9), Baihui (DU20) and Yintang (EX-HN3). In SA (Sham-acupuncture group), they will be provided non-acupuncture treatment on the same acupoints as those used in the TA group. Patients randomized in MC (Medication group) group will be given aspirin enteric-coated tablets and atorvastatin calcium tablets. The treatment will last for 12 weeks. This paper mentioned that the total plaque volume (PV) and the grey-scale median (GSM) are primary outcomes. Furthermore, secondary outcomes consist of intima-media thickness (IMT), lipid levels, apolipoprotein A-IV level, platelet count (PLT), fibrinogen (FIB) and platelet aggregation rate (PAR).

Generally, the paper is quite well written and there are number of general problems with the manuscript that need some revision. I recommended Below are my comments by section.

Title and abstract

The title is appropriate for the content of the article. However, I suggest the present new title instead of previous one:
Safety and Efficacy Assessment of Acupuncture Treatment for Carotid Atherosclerotic Plaques: Study Protocol for A Randomized, Single Blinded, Controlled Clinical Trial.

Although the abstract summarized the content of the article very well, it need some minor revision to include enough information. In the background section line 23, mention the importance of the present study and how it differs from previous works. In addition, give a summary of what you want to do. Furthermore, in line 29, it is better to add the setting of study: "This is a three-arm randomized clinical trial in China".
Background

Generally, the first part of the introduction should be summarized: I suggest that authors reform it into three main paragraphs: First, a brief definition of atherosclerotic disease, with some statistics in China, and its burden. Second, a brief description of possible primary, secondary, and tertiary preventions. Third, the studied role of acupuncture in atherosclerotic disease.

Line 73, the Study was performed in China. So, it's necessary to talk about statistics in the Chinese population, after referring to American population.

Line 89, a bit more information about acupuncture and acupoints would be needed and useful and provide more details.

Line 93, please mention how your study will advance medical practice and the health of humankind. In other word, highlight the gaps in current understanding, why the research will be carried out and the novelty of the manuscript.

At the end of this section (line 95), authors talked about study method, which is not acceptable here. Please omit this part, this could be visited in method part.

Methods

In study design section, please explain the design, which I think it should be parallel. Also describe why the study design proposed is the best way to answer the research question.

In line 109 mention the total sample size.

In intervention section, authors mentioned moxibustion, what was the exact type of this procedure? Direct or indirect? Please define it in the acupuncture method. Was it possible not to use moxibustion with acupuncture, as it may skew the results? The authors did not explain it in interventions.

In SA group part, did the authors asked patients about the history of performing acupuncture, especially in SA group? As a known history of acupuncture might affect the blinding procedure.

Line 152, how did you decide on the number of subjects in each group? Also how will the subjects be found?

Line 118, you need to cite a reference.

Line 124, Please add gender along with the age of the patients.

According to safety assessment part, what will you do to reduce risk and what will happen if adverse events occur.

According to trial status part, I checked the information in the Chinese clinical trial registry (protocol number ChiCTR1800019259) there are some differences, so please confirm the details in this protocol. In inclusion criteria, you state that low-desity lipoprotein (LDL) should be from 2.59 mmol/L-8.0 mmol/L (line 122), also you mention more than 5 plaques in exclusion criteria; they are different to the information of Chinese clinical trial registration. Furthermore, you mention hyperlipidemia (&gt;8.00mmol/L), Triglyceride greater than 10.0mmol/L and allergies as exclusion criteria in the clinical trials registery - please add to the protocol if this is correct. In protocol, age older than 70 years is an exclusion criterion which is different to the information in the clinical trials registry (older than 60 years).
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:

Acceptable

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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No