Reviewer's report

Title: Danggwijagyaksan for climacteric syndrome in peri- and postmenopausal women with a blood-deficiency dominant pattern: study protocol for a randomized, double-blind, placebo-controlled pilot trial

Version: 0 Date: 18 Oct 2017

Reviewer: Shu Wang

Reviewer's report:

This is a protocol for a randomized, double-blind, placebo-controlled pilot clinical trial aiming to explore the safety, efficacy and feasibility of Danggwijagyaksan (DJS) for improving climacteric syndrome in peri-and postmenopausal women with a blood-deficiency dominant pattern. This is a pilot study of future rigorous RCT supporting DJS for peri-and postmenopausal women with a blood-deficiency dominant pattern.

There are several concerns about the manuscript:

- Background: Is there previous survey illustrating epidemiological data about pre- or post-menopausal women diagnosed of blood deficiency? If so, please give a brief description.

- Intervention: Is there any contraindication for Danggwijagyaksan? Is so, could these patients be recruited in your study?

- Outcome measures: blood deficiency scoring system (BDSS) will be used as diagnosis standard of blood deficiency during screen period and as a part of outcome measures. Is there any evidence for its validity or reliability? Since the original reference the authors provided might not be applicable through online material, please add more details of BDSS.

- There is no evidence supporting independency or blindness in statistical analysis, data management and monitoring, which could lead to underlying bias.
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:

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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.

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