Reviewer’s report

Title: Efficacy and safety of Guhong injection for treating the Coronary microvascular disease: study protocol for a randomized controlled trial

Version: 0  Date: 14 Nov 2019

Reviewer: Kirsty Loudon

Reviewer's report:

This is the editorial comment.

This is a comprehensive protocol to evaluate the use of Guhong injection to treat Coronary microvascular disease. The SPIRIT checklist has been completed but there is some information that is missing in the protocol manuscript, highlighted below. The English also needs to be checked as it is not completely correct. I have highlighted few points in comments, but this is not comprehensive. For instance in the first two sentences of the abstract:

1. Coronary microvascular disease (CMVD) refers to cardiovascular diseases with normal coronary angiography but evidence of myocardial ischemia or microcirculation lesions, often presenting as angina pectoris attack. Coronary artery of microtubules dysfunction is one of the pathogenesis of coronary heart disease, but the occurrence and development and the current of CMVD intervention therapy remains to be further researched.

THIS would read better as:
Coronary microvascular disease (CMVD) CAN BE DESCRIBED AS cardiovascular disease with normal coronary angiography but evidence of myocardial ischemia or microcirculation lesions, often presenting as angina pectoris attack. Coronary artery of microtubules dysfunction is the pathogenesis of coronary heart disease, but the occurrence and development and the current of CMVD intervention therapy NEEDS further research.

2. In abstract please write out "ecg" and explain "TCM syndromes"- what does this mean?
3. Page 3, line 5 "At present, the treatment scheme of western medicine" better is "regime" instead of "scheme"
4. Page 3, line 24 etc What type of injection is given - subcutaneous, intra-dermal, Intra-muscular and where are they usually given? ITEM 11a SPIRIT checklist - GIVE SUFFICIENT DETAILS TO ENABLE REPLICATION, INCLUDING HOW AND WHEN THEY WILL BE ADMINISTERED.
5. Page 4, line 63 "truthfully throughout the study" delete "truthfully" incorrect usage.
6. Page 5, line 27 "Patients with allergic to Guhong injection" EDIT to "patients who are allergic to Guhong injection"
7. Randomisation and blinding - English needs to be improved.
8. Page 6 line 3 "Once banned drugs are used, patients will be dropped out of the study." - have they signed a consent form that their data can still be used up to th
9. Page 7, line 16 Secondary outcomes - TCM symptoms - suggest you insert the words (Table 3) so reader knows to look at this when comes up in the manuscript.
10. Page 8, line 51 Data management and statistical analysis - I am not clear if the outcome assessors and data managers are blinded. I know those giving the injection are blind to content - Item 17a SPIRIT checklist please give additional information.
11. Item 17b - SPIRIT checklist- I cannot see information about "unblinding" please add into the manuscript.
12. Quality control and monitoring - page 9, line 28 "shedding" is the wrong word - think you mean "lost to follow up"

13. Page 10, line 57 - do you mean PATIENT medicine not patent? Also page 7 and throughout the document - please check.

14. Sometimes you say TCM syndromes and sometimes you say symptoms - I think you mean symptoms - please check the whole manuscript. Eg page 6, line 14

15. Item 21b - SPIRIT checklist I cannot see any interim analyses and stopping guidelines on page 8 or elsewhere in the manuscript. Please add this information.

16. Item 14 SPIRIT checklist - I cannot see any information on sample size calculations on page 4 or elsewhere in the manuscript. Please insert this into the manuscript with estimated number of participants needed to achieve study objectives AND HOW IT WAS DETERMINED, INCLUDING CLINICAL AND STATISTICAL ASSUMPTIONS SUPPORTING ANY SAMPLE SIZE CALCULATIONS.

* References: There were 4 articles that could not be checked, please check format for websites, include date checked and ensure sufficient information as in guidelines below. Seven articles are not validated (https://trialsjournal.biomedcentral.com/submission-guidelines/preparing-your-manuscript/study-protocol/#references).

**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:

- Not suitable for publication unless extensively edited

**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.

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Please complete a declaration of competing interests, considering the following questions:

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No