Reviewer’s report

Title: Tongmai Yangxin intervening in myocardial remodeling after PCI for coronary heart disease: study protocol for a double-blind, randomized controlled trial

Version: 0 Date: 16 Jan 2020

Reviewer: Kirsty Loudon

Reviewer's report:

This is the editorial comment.

This is an interesting trial protocol of a randomised trial to determine if the Tongmai Yangxin pill can improve myocardial remodelling after PCI for coronary heart disease.

1. The English language in the manuscript requires checking by a native speaker. A few examples of incorrect spelling are outlined below but these are only a few.

Starting with the second sentence of the abstract I am unclear what exactly you mean.

The third sentence is also not grammatically correct.

Page 4, line 13 the correct word is "until" not "till". And that is just at the start.

Inclusion Criteria is misspelt so please check manuscript thoroughly before resubmission.

Page 4 the word "didn't" is used - more formal English is better so write out "did not" though I would say first exclusion criteria is: "Patients with multiple coronary artery branch lesions that did not receive elective PCI within 10 days."

I would check language used with a cardiac specialist to ensure correct terminology used.

Page 7 it is "urinary" not "uninary" but urinary pregnancy is incorrect description.

2. It is important to write out in full all abbreviations the first time they are used i.e. HF and TCF and TMXY in the abstract and also the protocol manuscript i.e. page 3 line 47 LVEDVI= LVEDV/BSA etc

3. Table 1 - suggest you do not use abbreviations 6MWT and SAQ but write out in full. Check English. Figure 1 - check English "routine urinalysis" and "data analysis"

4. Once the English is improved I will then be able to comment on the Background and Rationale for the trial.

I will use the SPIRIT checklist to structure further comments on the manuscript.
SPIRIT checklist - It is not acceptable for Trials journal for the authors leave any items blank or with N/A or incomplete i.e. X in the SPIRIT checklist. Further information giving rationale is required. Please either edit the protocol and insert page numbers in the checklist or insert relevant information in the SPIRIT checklist.

Unfortunately, while you have completed the SPIRIT checklist you have combined many of the items e.g. 2a and b, as well as items 5a, b, c and d etc. Each of these items are important and it would have been much easier for me to review and you to ensure the protocol was complete if you had used the complete SPIRIT checklist.

Item 1: The title is unclear, I do not know exactly what you mean by "remodelling". Please edit. The title also does not contain the word randomised controlled prior to "trial" and insert the word "protocol". You could say: Protocol for a double blind randomised controlled trial. The title should identify the study design (currently no), population (coronary heart disease but any particular group who have that condition?), interventions (Tongmai Yangxin pill and placebo).

Item 5b: Who is the trial sponsor? Ministry of Science and Technology of the People's Republic of China - if this is correct then please insert contact information - usually a contact email can suffice, some protocols insert the name of an individual. It is the role of sponsor(s) to ensure that proper arrangements are in place to initiate, manage and report on a study. Sponsors must also ensure that appropriate indemnity is in place before research begins.

Item 10: page 5 (3) please define Killip classification so everyone can understand this exclusion criteria; (6) write out abbreviations please and ensure in list at the end of the manuscript.

Item 11c: page 8 Adherence - please write out in full ¥100 Chinese yen. When you discuss blinding earlier you do not mention "participants" or "attending physicians" or "patients" so who gets ¥100? I suggest you use consistent language - are the patients the participants? Chose one word and just use that word.

Item 12: how will you measure the primary outcome Left ventricular end-diastolic volume index (LVEDVI =LVEDV/BSA)? And when will you measure it? Please put in time point for each outcome, primary and secondary outcomes. SPIRIT strongly recommends that you give an explanation of the clinical relevance of the your chosen efficacy and harm outcomes. Which biological indicator will you use and what is "an experiment event rate"? Please clarify.

Item 14: sample size - please insert the reference: "A previous study suggested that the LVEDV of following AMI patients within 24h-72h is about 162±57ml, and 162±57ml at 6 months[?]. Is this another reference? "According to the pilot experiment of TMYX, the LVEDVI maybe reduced 4 ml/m2 within 3 months." Please insert into the reference list and add here. Again, English is incorrect.

Item 15: page 4 requires far more information. Are there any other methods for recruitment being used? Where will the advertisements be placed? As posters in hospitals, in bus stops, newspapers, how often will they advertisements run if in the media.

Item 17a: Blinding (masking) NOT "Blindness".

Item 17b: Please spell out AES, as first time used. The 2nd sentence is incorrect English.
Item 20a: you state a 3rd party will be used does this mean blinded to allocation? See 17a.

Item 20b: Are you going to do any subgroup analyses (e.g. subgroup and adjusted analyses)

Item 20c: What are you going to do when you detect missing data? Please insert the information into the protocol manuscript.

Item 26a: Who will obtain informed consent or assent from potential participants or authorised surrogates, and how? We need to know who will actually recruit patients after they respond to the advertisement (note not "ad").

Item 28: you state that the "we also supported by Tianjin Zhongxin Pharmaceutical Group Co., Ltd.; Le Ren Tang Pharmaceutical Factory". I believe you should consider stating this under "declaration of interests" as it appears that there is money being paid for the trial and each study site by the manufacture of the drug being tested. Does this money go directly to pay salaries for the trial or are materials paid for by these drug companies? You state no COI but currently your statement is unclear. If any funding that is paid to the institutions is received this needs to be declared under Item 28 so readers know can read this under declarations. I note under Item 5c that the funder will have no part in study design, etc: "didn't take part in the design of this study and will not have any role during its execution, analysis, interpretation of the data, or the decision to submit results."

Item 30: Provisions for post-trial care - you could state "There is no anticipated harm and compensation for trial participation" and it would be helpful to know if there will be any provision for post-trial care.

Item 33: Item 33: See above 26b there will be no biological specimens collected OR if applicable "For this SPIRIT item, please add information on plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trials and for future use in ancillary studies."

References: There were 3 articles that could not be checked, please check format for websites, include date checked and ensure information as in guidelines below. Five articles were 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:

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.

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

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No