Author’s response to reviews

Title: Efficacy of post-procedural oral hydration volume on risk of contrast-induced acute kidney injury following primary percutaneous coronary intervention: study protocol for a randomized controlled trial

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Response to Reviewers

Jochen Raimann

Dear editor from Trial® Editorial Office,

Thank you very much for giving us an opportunity to revise our manuscript. We appreciate the editor and reviewer very much for their constructive comments and suggestions on our manuscript entitled “Efficacy of post-procedural oral hydration volume on risk of contrast-induced acute kidney injury following primary percutaneous coronary intervention: study protocol for a randomized controlled trial” (TRLS-D-18-00963).

We have studied the reviewer’s comments carefully. According to the reviewer’s detailed suggestions, we have made a careful revision of the original manuscript. All revised portions are marked in red in the revised manuscript which we would like to submit for your kind consideration.
Dear editor and reviewer:

Thank you for your letter and the reviewer’s comments on our manuscript entitled “Efficacy of post-procedural oral hydration volume on risk of contrast-induced acute kidney injury following primary percutaneous coronary intervention: study protocol for a randomized controlled trial” (TRLS-D-18-00963). Those comments are very helpful for revising and improving our paper, as well as the important guiding significance to other research. We have studied the comments carefully and made corrections which we hope meet with approval. The main corrections are in the manuscript and the response to the reviewer’s comments are as follows (the replies are highlighted in blue).

Replies to the reviewer Thomas Kitzler’s comments:

Custom Review Question(s)
Level of interest
Please indicate how interesting you found the manuscript: An article of importance in its field.  
Response: Thank you very much. We studied the effects of post-procedural oral hydration regimen, which is a potential strategy for CI-AKI prevention among patients with STEMI at very high risk.

Quality of written English
Please indicate the quality of language in the manuscript: Needs some language corrections before being published
Response: Thank you very much. We had the paper edited using Elsevier Language Editing Services. We will attach the certificate with the revised manuscript.

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. – Acceptable
Response: Thank you for the scrutiny.

Statistical review
Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report. - No, the manuscript does not need to be seen by a statistician
Response: Thank you for the scrutiny.
Comments to Author:
In this study protocol, the authors outline a secondary analysis of the database from the ATTEMPT study. The here proposed study aims to assess the association between post-procedural oral hydration and contrast induced acute kidney injury in patients with ST-elevation myocardial infarction by using multivariable analysis.
Response: Thank you very much. Our study will determine the effects of post-procedural oral hydration on CI-AKI following primary PCI, which is a potential strategy for CI-AKI prevention among patients with STEMI at very high risk.

There are several strengths to this study protocol:
1) The study protocol seems appropriate for the target journal.
2) The main hypothesis is clearly stated and the study protocol addresses a clearly focused issue; the primary and secondary outcomes are clearly described.
3) The proposed statistical analyses seem appropriate.
4) The outcome of this trial is of interest to the community and may be useful for the development of treatment strategies that ameliorate the development of CI-AKI.
Response: Thank you very much. We believe that this paper will be of interest to the readership of Trials because this is an interesting manuscript on development in medicine.

The major concern with this trial is that this is a secondary database analysis of a study that was not designed to directly address the main objective of the study protocol proposed here; however, this limitation is also being recognized by the authors.
Response: Thank you for your careful reading of our manuscript. As mentioned in the Limitation, this is a secondary analysis, which is not able to conclude a causal relationship. Future large-sample, well-designed RCTs are required to confirm and update the findings of this secondary analysis. However, to the best of our knowledge, this is the first prospective, sub-analysis to investigate the effect of oral hydration on the prevention of CI-AKI in high-risk patients undergoing primary PCI.

I have only a few minor comments:
1) The authors reference the original ATTEMPT study when listing inclusion and exclusion criteria, but they should consider listing them in this study protocol directly.
Response: Thank you for your valuable and thoughtful comments. We are sorry for not describing the inclusion and exclusion criteria directly. According to your helpful advice, we have rewritten this part in the section of Methods.

2) Is it useful to provide a power calculation for the secondary data analysis? My understanding is that this can also be done for secondary data.
Response: Thank you for your professional advice. We agree that we should provide a power calculation in the manuscript. According to your helpful advice, we have rewritten this part in the section of Statistical Analysis by highlighting the content in red.

3) The current trial status is unclear. The authors state January, 2018 as an estimated completion date, while on clinicaltrials.gov the estimated completion date is July 2017. In the protocol, however, it says that recruitment is ongoing as of Oct, 2018 with 555 patients, which is only 5 patients short from the estimated enrollment of 560. Please clarify.
Response: Thank you for the scrutiny. The RESCIND –1 ATTEMPT Trial (Protocol version 2.0, 11th
June 2014) enrolled the first participant on 1st July 2014. On clinicaltrials.gov, the estimated completion date was in July 2017. However, since the difficulties of enrollment and quality control, we are behind schedule. That is the reason for changing the expected completion date. As of October 24, 2018, recruitment is ongoing with 555 patients randomized at 15 centers in China. The follow-up will be carried on for 1 year after the initial enrollment. The completion time of the trial is expected to be December 2019. We have revised the original description and highlighted in red.

4) While the authors state that they will address possible confounders, they do not list the confounders which they are controlling for, except for the different IV hydration strategies. Please list the possible confounders that are being measured during the trial.
Response: Thank you for your professional advice. We agree that we should discuss the possible confounders that may be the risk factors of CI-AKI in the manuscript. We have revised the Methods and listed the possible confounders being measured by highlighting the content in red.

5) On page 5, line two, the authors reference one publication after referring to the outcome of several previous meta-analyses. Please provide the original references of these meta-analyses.
Response: Thank you for the scrutiny. We have provided all necessary citations in the revised manuscript and highlighted in red.

Once again, thank you very much for your constructive comments and suggestions which would help us both in English and indeed to improve the quality of the paper.

Kind regards,

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