Reviewer’s report

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

Version: 0 Date: 25 Feb 2019

Reviewer: Thomas Kitzler

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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.

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.

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.

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.
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.
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.
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.
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.

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