Author’s response to reviews

Title: The effect of regional citrate anti-coagulation on the coagulation system in critically ill patients receiving continuous renal replacement therapy for acute kidney injury - an observational cohort study

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Responses to editor’s comments

1. You state that funding for the study was received from Fresenius Kabi; however, they did not have any involvement in the design of the protocol. Can you please confirm whether they have checked and approved this study protocol prior to granting funds? Do they have an independent review panel?

I confirm that the study received funding from Fresenius Medical Care UK Ltd. The company did not have any involvement in the design of the protocol. As outlined in the funding letter, I applied to Fresenius Medical Care UK Ltd and submitted the final protocol. The application and protocol were initially peer-reviewed by an independent “Investigator Driven Study Evaluation Committee (IDSEC)”. They checked and approved the protocol prior to granting funds. The application and protocol were subsequently reviewed again by a team of Fresenius Medical Care personnel, and funding was granted. (please refer to funding letter)

I have revised the funding section accordingly. (page 14)
2. Can you please include a completed SPIRIT guideline checklist as an additional file. We also encourage you to refer to the STROBE guidelines to ensure that your manuscript reporting is complete and therefore, reproducible.

A SPIRIT guideline checklist has been completed and submitted as an additional file.

3. Can you please include the trial registration date in the Abstract. See our online Study Protocol manuscript formatting guidelines for further guidance.

The study was registered with ClinicalTrials.gov on 10th June 2015 (NCT02486614). We have included the date in the manuscript and abstract. (pages 2 and 15)

**FORMATTING CHANGES:**

1. Requesting ethics and funding proofs:

As you may be aware, it is the policy of the journal not to peer review study protocols where ethical and external funding approval have been obtained, as these processes usually involve peer review and as there is little possibility to change a protocol after enrolment begins.

Therefore, could you please respond to the following points below and provide the requested responses in your cover letter.

1. Ethical and Funding Approval Documentation Before we can proceed with your submission, can you please forward copies of all ethical approval and funding approval for our records. These documents should be sent as email attachments to the following email address, BMCSeriesEditorial@biomedcentral.com.

I have sent a copy of the funding letter and the letter of approval from the Ethics committee to the email address BMCSeriesEditorial@biomedcentral.com.

2. Funding

A study is considered to be externally funded if the authors have been awarded a grant for the study by a major funding body (e.g. governmental funding/ award from a charitable foundation). If a study has not received external funding, then the study protocol will be sent for peer-review
with a member of our Editorial Board. If a study has received funding/assistance from a commercial organization, this should be clearly stated in the 'competing interests' section of your manuscript, and the study protocol will be sent for peer-review by a member of our Editorial Board. Can you please confirm whether your study protocol has undergone peer-review by the funding body.

I confirm that the study received funding from Fresenius Medical Care UK. As outlined above, the company did not have any involvement in the design of the protocol.

The application and protocol were initially peer-reviewed by an independent “Investigator Driven Study Evaluation Committee (IDSEC)”. They checked and approved the protocol prior to granting funds.

The application and protocol were subsequently reviewed again by a team of Fresenius Medical Care personnel. (please refer to funding letter) The funding section has been revised accordingly.

I have revised the section “Competing interests” and stated explicitly that the study was funded by Fresenius Medical Care UK Ltd. (page 13)

3. Study Status

The protocol must be for a study that is ongoing. An 'ongoing' study is defined as one where the investigators are still collecting, or analyzing data. Can you please confirm what stage your study is currently at.

I confirm that the study is still ongoing. We have now reached our recruitment target and will proceed with the batch analyses in the near future as soon as the necessary reagents have been purchased.

4. Related Articles

Can you please clarify whether any publications containing the results of this study have already been published or submitted to any journal. If so, can you please provide a list of the related articles.

I confirm that we have not analysed any samples yet and have not written any manuscripts or reports.

5. Declarations
In accordance with BioMed Central editorial policies and formatting guidelines, all submissions to BMC Nephrology must have a Declarations section which includes the mandatory sub-sections listed below.

The Declarations section has been revised and now contains the sections:

- Ethics approval and consent to participate
- Consent to publish
- Availability of data and materials
- Competing interests
- Funding
- Authors’ Contributions
- Acknowledgements
- Authors' Information

6. Title page

It should contain, at minimum, the names, institutions, countries and email addresses of all authors, and the full postal address of the submitting author.

The title page has been revised and the email addresses of all authors have been added.