Author's response to reviews

**Title:** The efficacy and safety of acupuncture for cerebral vasospasm after subarachnoid hemorrhage: Study protocol for a randomized controlled trial

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**Author's response to reviews:** see over
Dear Altman,

We thank the editors and reviewers of *Trials* for taking their time to review our article, “The efficacy and safety of acupuncture for cerebral vasospasm after subarachnoid hemorrhage: Study protocol for a randomized controlled trial”.

The manuscript was revised by according to your opinion on the basis of reviewer’s comments. Please examine a reply corresponding to the reviewer’s comments and the corrected manuscript. The changes are summarized below:

**Editorial requests:**

1) Can you please add the email address of each author to the title page.

   According to your comment, we added email addresses of all authors (page 1-2).

2) Please include a list of abbreviations used in the manuscript and their meanings.

   We added abbreviations section before competing interests (page 16).

3) Please add the following statement to the end of your Author’s Contributions section: “All authors read and approved the final manuscript.”
Thank you for your comment. We added the statement to the manuscript (page 17).

4) Please include an acknowledgement section at the end of the manuscript before the reference list. Please acknowledge anyone who contributed towards the study by making substantial contributions to conception, design, acquisition of data, or analysis and interpretation of data, or who was involved in drafting the manuscript or revising it critically for important intellectual content, but who does not meet the criteria for authorship. Please also include the source(s) of funding for all authors. Authors should obtain permission to acknowledge from all those mentioned in the Acknowledgements. Please state clearly whether or not you have funding in the acknowledgement section. If there is no funding, please state this.

There is no one to add except co-authors and we added the funding source in the acknowledgement section (page 17).

Reviewer’s comments:

1. The block size of randomization should not be reported in a protocol. Reporting it takes the risk of unbinding, by people who know how block works in a randomization, then they can pick the group they want.
We little suspected that it would affect the blinding. We deleted the phrase in the manuscript according to your opinion. Thank you (page 8).

2. The experimental group will actually receive electro-acupuncture and intradermal acupuncture. No need to repeat acupuncture separately, unless the acupuncture is specially manipulated. Otherwise, it may cause confusion.

In our pilot study [24], we confirmed the possibility of manual acupuncture in preventing the occurrence of cerebral vasospasm after SAH. To strengthen effectiveness of acupuncture, we chose electro-acupuncture and intradermal acupuncture in this study. After electro-acupuncture, intradermal acupuncture will be inserted and maintained for 1 day. We adopted intradermal acupuncture to continuously stimulate the acupuncture points.

3. The mock TENS is used without electrical stimulation, what will you do to maintain blinding if the patients have experience of electro-acupuncture? Will you exclude those patients in the screening phase?

That is a good point. According to your comment, we decided to exclude the patients experienced electro-acupuncture. We added it in exclusion criteria. Thank you (page 9).
4. In the primary outcome, how did you define “an unaccountable new focal neurological deficit”? Through specific symptoms and signs of the patients, or by TCD/CT/MRI, or by a neurological deficit scale assessment? This needs more details.

DIND is defined as an unaccountable new focal neurological deficit lasting > 2 hours with either angiography or transcranial Doppler findings. When any neurological changes occur, we check whether it has been occurred due to vasospasm by TCD, CT angiography or MRI. If the results confirm vasospasm, it is suggested that DIND has occurred. We modified the sentence in detail in assessment section (page 11).

5. It will be easier to read if you provide a flow chart of the study.

We made a flow chart, Fig. 1.

6. Although the statistical analysis is technically correct, it misses lots of important information which might cause a biased result. For example, the patients will receive conventional treatments that include different interventions and different dose of a specific medication between patients, so in your statistical model, if you could add these as covariates, it would be much better.
Thank you for your comment. We plan to do multiple regression analysis to control for possible confounding factors (e.g. age, Hunt and Hess Scale, modified Rankin scale, endovascular coiling or surgical clipping, etc.). We revised the statistical analyses section (page 15).

We express deep thanks to the professional and valuable comments and suggestions. We hope that this revised manuscript will meet the publication requirements of Trials.

Thank you again for the constructive comments.

Sincerely yours,

Seong-Uk Park