Author's response to reviews

Title: Interaction and Efficacy of Keigai-rengyo-to extract and acupuncture in male patients with acne vulgaris: A study protocol for a randomized controlled pilot trial

Authors:

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Author's response to reviews: see over
Dear Editors-in-Chief,

Thank you for your prompt review (version 2).
Enclosed please find a revised manuscript (version 2) entitled “Interaction and Efficacy of Keigai-renyo-to extract and acupuncture in male patients with acne vulgaris: A study protocol for a randomized controlled pilot trial” (MS: 1657729038508789) by Kyu Seok Kim and Yoon-Bum Kim along with 1 table and 1 figure, which we wish to resubmit to the “Trials” for publication.

In accordance with reviewer's comments and recommendations (version 2), we revised our paper (we highlighted all new changes with colored text in the revised manuscript.) and in this cover letter, we would describe in detail how each of the reviewer concerns were addressed in this manuscript as follows.

Reviewer’s report and our revision:

1. The randomization section remains vague. The authors have to specify step-by-step procedures to prevent researchers guessing allocation before a patient is unambiguously registered on study or changing allocation after registration. A vague reference to an excel spreadsheet being password protected is insufficient. Examples of detailed descriptions of allocation concealment can be found at www.consort-statement.org or http://www.ncbi.nlm.nih.gov/pubmed/17022927.

✓ → Thank you for your kind comments. Referring to the detailed descriptions of allocation concealment at www.consort-statement.org and http://www.ncbi.nlm.nih.gov/pubmed/17022927, we added and revised the following contents to ‘Randomization and blinding’ part.

➢ “...Randomization will be performed at a site remote from trial location. Random numbers will be generated by a computerized random-number generator through the block-randomization method of a software program (Excel, Microsoft Office 2007) for sequence generation and we will make two separate database: a “patients” database that lists basic information such as patient name, contact details and so on, and a “randomization” database that holds data on which patients have been registered on trial along with their allocations. The “patients” database will be accessible to any researcher whereas the “randomization” database will be password protected so that it will be accessible only by the principal investigator and a nominated statistician [31].”

✓ → We added the following contents to ‘References’ part and revised the reference number (from #31 to #32 and from #32 to #33)


In addition to reviewers’ comments and recommendations, we revised partly to make our point clear.
If you think we have to revise our paper in addition, please contact us by email at any time.

Thank you for your kind considerations in advance and I am looking forward to hearing a positive reply from you soon.

Sincerely yours,
Kyu Seok Kim O.M.D. Ph.D