Author's response to reviews

Title: The efficacy and safety of Gantong Granules in the treatment of common cold with wind-heat syndrome: study protocol for a randomized controlled trial

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Author's response to reviews: see over
Dear Editor,

Thank you very much for your letter and the comments from the referees about our paper submitted to The efficacy and safety of Gantong Granules in the treatment of common cold with wind-heat syndrome: study protocol for a randomized controlled trial (MS Number 1176314758151028). We have checked the manuscript and revised it according to the comments.

Sincerely yours,

Jie Min

Response to reviewer as follows:

1. Gantong Granules is a Chinese herbal compound. The exact ingredients in the Gantong Granules were showed in the Background section in page 4. The content of each herb in the compound is patented.

2. The duration of symptoms is defined as the time from study enrollment to the time when the patient feels not sick at all. This is a randomized controlled trial and the bias from different degree of severity will be minimized.

3. Due to special appearance, smell and taste of Chinese herbal medicine, the preparation of placebo is very difficult, especially for granules and decoction. To offset bias from sense, some clinical trials in China and Japan used placebo made of 10-times and 20-times diluted original drug. In this trial, we used 10-times dilution to make sure that placebo had the similar
appearance, smell and taste as test drug. The action mechanism of herbal medicine is very complicated and effective chemical composition is not fully clear. For this reason, we did not conduct successive dilution trial to find minimum dose of original drug which do not have any pharmacological nor clinical effects. In China, some researcher found that 10-times diluted original herbal medicine had no pharmacological effect on their experiments [1]. Based on the previous studies, the minimal effective dosage of Gantong Granules is 5g. The lower dose will be considered as clinically ineffective. So, we think it is the better choice to ensure compliance and implementation of blind method. We added further explanations about placebo in the Interventions section.

4. The primary outcome in the the phase II clinical trial was the percentage of symptom score reduction. So far, the duration is well-recognized as the primary outcome measures in common cold.

5. English has already been improved.

6. We declare that the sponsor had no role in the study design, data collection, analyses, and decision to submit the manuscript. Although the placebo is the diluted form of the original drug, it has no clinical effect.

Reference