Author's response to reviews

Title: Acupuncture for Dry Eye: a Multicentre Randomised Controlled Trial with Active Comparison Intervention (Artificial Tear Drop) Using a Mixed Method Approach Protocol

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Version: 3 Date: 4 November 2010

Author's response to reviews: see over
Cover letter

Reply to the review comment

Dear Dr. Lawrence Friedman

We are very pleased with your review of our protocol manuscript. In the following we will try to address all your suggestions adequately. We hope you may be satisfied with our response to your questions and remarks.

Thank you very much.

Best regards,

Tae-Hun Kim on behalf of all authors
Reviewer's report

Title: Acupuncture for Dry Eye: a Multicentre Randomised Controlled Trial with Active Comparison Intervention (Artificial Tear Drop) Using a Mixed Method Approach Protocol

Version: 2 Date: 2 November 2010

Reviewer: lawrence friedman

Reviewer's report:

I have a couple of issues that should be clarified. First, because this is a trial with an active control (artificial tears), how good is the evidence that the active control is useful for dry eyes? Is there just the one trial cited, or is there other evidence?

1. Artificial tear is one of the first choices in a treatment recommendation for dry eye. Because the strategy for treating dry eye is to ease ocular discomfort and to improve quality of life, to recover the ocular surface inflammation and tear film stability\(^1\), artificial tear can be recommended as an active treatment option in medical practice. According to a survey report of ophthalmologists, preservative-free artificial tear was most frequently used for moderate to severe dry eye patients among various treatment modalities in Korea\(^2\). In this context, we chose preservative-free artificial tear as an active comparator in this research. We added the reason for the choice of artificial tear as a active comparator in this manuscript (page 7, paragraph 3)

In the current trial, if acupuncture is not shown to be superior to artificial tears, will noninferiority be claimed? If so, what delta will be used?

2. Basically, we designed this trial for testing the superiority of acupuncture treatment comparing to artificial tear, so we will not conduct a statistical analysis for testing non-inferiority, even though acupuncture is not shown to be superior to artificial tears.

Second, the primary outcome will use the OSDI, translated into Korean. Has this instrument been successfully and validly used in other translations?

3. There are several tools for evaluating symptoms or disability related to dry eye in Korea. However, there is no tool for dry eye of which validation test for translation in Korean were finished currently. Korean version of OSDI has been used in clinical trials since 2006\(^3\) and it is now widely used for practice and research\(^4\)\(^-\)\(^6\). We agree that we should use a pre-validated questionnaire. But it was the second best plan for us in current situation to use pre-translated and now widely-used tool for this research. We added this in the manuscript. (page 7, paragraph 4)


Two minor issues: a) In the Abstract, Methods section lines7, rather than “treated” might say “used”;

4. The word “treated” were changed into “used” in the abstract (page 2, paragraph 2)

b) In the Acknowledgements, it is said that the study “was” supported. Is the study
completed? If not, should say that the study “is” supported.

5. The word “was” were changed into “is” in the Acknowledgements (page 2, paragraph 2)