Reviewer's report

Title: Efficacy and Safety of Intra-articular Injections of Sodium Hyaluronate (Hyalgan) in the Treatment of Osteoarthritis of the Knee A Randomized, Controlled Trial in the Asian Population

Version: 3 Date: 23 May 2011

Reviewer: Kåre Birger Hagen

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Efficacy and Safety of Intra-articular Injections of Sodium Hyaluronate (Hyalgan®) in the Treatment of Osteoarthritis of the Knee A Randomized, Controlled Trial in the Asian Population.
Teng-Le Huan et al

I consider the manuscript as relevant and interesting.

Major compulsory revision:
I think that the manuscript needs to be revised regarding the presentation of the results and the interpretation of the results. The rationale for performing a RCT is to compare the effects between the intervention group and a comparison group. Moreover, there is now a general consensus within the scientific community that “for each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)”. Here this is pretty simple, the results for both groups and the between group differences in change from baseline to week 25 should be presented for the pre-defined primary and secondary outcomes should be presented (preferably in a table). I’m aware that some of these are presented in the text not at all in the abstract. P-values does not say anything about the size of the effect. My other main concern is the interpretation of the results. As fare as I can see the authors have not at all touched the question whether a difference on 8 mm (on a 0 to 100 scale) is a clinically relevant effect. I really think the authors should reconsider their conclusion that “These results support the efficacy of sodium hyaluronate for relief of OA knee pain.

Minor essential revision:
In my opinion the standard of reporting needs to be improved. I would like to draw the authors attention to the CONSORT statement. There is a checklist for reporting that the authors can download from the web. As fare as I can see now essential details such as mechanism used to implement the random allocation sequence (such as sequentially numbered containers), and description of any steps taken to conceal the sequence until interventions has not been described.

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1. Is the question posed by the authors well defined? YES

2. Are the methods appropriate and well described? CAN BE IMPROVED (MINOR ESSENTIAL REVISION).

3. Are the data sound? YES

4. Does the manuscript adhere to the relevant standards for reporting and data deposition? CAN BE IMPROVED (MINOR ESSENTIAL REVISION).

5. Are the discussion and conclusions well balanced and adequately supported by the data? NO (MAJOR COMPULSORY REVISION)

6. Are limitations of the work clearly stated?

7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished? YES, AS FARE AS I CAN SEE

8. Do the title and abstract accurately convey what has been found? THE TITLE DOES NOT REFLECT STUDY RESULTS. THE ABSTRACT DOES NOT EXACTLY REFLECT WHAT HAS BEEN FOUND (MAJOR COMPULSORY REVISION)

9. Is the writing acceptable? YES

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.