Reviewer's report

Title: Comparison of Hyaluronic Acid and Corticosteroid intra-articular injections for the treatment of Osteoarthritis of the hip controlled with intra-articular injections with Bupivacaine. Design of a double blinded prospective randomized controlled study.

Version: 3 Date: 24 May 2010

Reviewer: Burkhard Leeb

Reviewer's report:

Major compulsory revisions:

Given the text the reviewer assumes that the primary endpoint of the study should be an improvement of the HHS in the HA and CS treated patients in comparison to the controls (Bupivacain) at month 6. To the reviewer’s knowledge there are insufficient data supporting a six month efficacy of CS injections into the hip. However, no difference between HA and CS injection is obviously expected by the authors. As far as the reviewer understood the protocol, one injection is intended per patient included. As the efficacy of a single HA injection into a joint is also not yet proven (even for knee joints), it remains doubtful whether it will be possible to meet this primary endpoint of six months.

First, the authors should indicate a clear primary endpoint and a distinct primary outcome measure (e.g. the HHS or the VAS) of the trial. Second, the reviewer would propose to reconsider, whether six months after the application of the study drugs would constitute an appropriate primary endpoint.

One of the inclusion criteria is chronic pain for the last three months. This statement in fact seems to be rather vague. A decisive value on the VAS pain for patients to be included is seriously proposed; e.g. 30 mm on the VAS at screening, and no improvement at the day of the injection. In addition, a threshold value on the HHS or the HOOS at the screening visit for patients to be included should be given.

To assume an ES of 0.4 for HA and CS treatment comes near the ES Zhang et al. found for PBO intra-articular injections in their meta-analysis of PBO responses in OA clinical trials. Therefore a reconsideration of the ES is strongly recommended. In addition, an anticipated drop-out rate of 10% can be regarded very optimistic in a six months hip OA trial. Therefore, the reviewer would recommend to reappraise the drop-out rate, and to increase the number of subjects to be included.

The writing can be regarded acceptable.

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.

**Declaration of competing interests:**

Dr. Leeb has received consultancy fees from TRB Chemedica, and IBSA.
Dr. Leeb was involved in clinical trials sponsored by IBSA.
Dr. Leeb has received speaker’s honoraria from TRB Chemedica, IBSA, Lacer-Spain and Biosaude-Portugal.