Reviewer's report

Title: Topical insulin-like growth factor-1 treatment using gelatin hydrogels for glucocorticoid-resistant sudden sensorineural hearing loss: a prospective clinical trial

Version: 1 Date: 14 September 2010

Reviewer: David J Lim

Reviewer's report:

GENERAL COMMENTS:
The treatment for sudden sensorineural hearing loss is an important clinical issue facing ENT specialists, largely due to the narrow window of the effective treatment; which can significantly impact the clinical outcome. The most common choice of treatment for sudden sensorineural hearing loss is the phased systemic glucocorticoid treatment, which should be started as early as possible. However, there is a group of patients who are resistant to the glucocorticoid treatment. In this study, the authors treated these patients with topical insulin-like growth factor-1 using gelatin hydrogel releasing methods, which they have developed, were found to improve hearing after treatment. All in all, this study is well conceived, well designed, and the analysis of the data is well within the accepted methods. The interpretation of the results also appears reasonable. However, there are several areas of clarification that would influence the interpretation of the results.

SPECIFIC COMMENTS:

1. The primary outcome measure is the measure of the hearing improvement. The endpoint is defined as change in a 5-frequency threshold average in one place, but in other place it is defined as mean hearing level (Page 10). It would help the reader if the same term was used to describe the endpoint throughout the paper (threshold improvement or mean hearing level improvement). (Minor Essential Revision)

2. On p. 9, the description of the sample size calculation could be clarified. First, the null hypothesis is considered an equivalence test; the methods should state that clearly. Second, the conceptual null hypothesis sentence should be stated prior to the sentence describing the conditions under which the sample size was calculated (e.g., the sentence about the binomial distribution). Finally, please clarify how many patients represent the 10% excluded. (Minor Essential Revision)

3. Some of the symptoms of presumed drug-induced adverse effect such as tinnitus, floating sensation also could be the disease related. For example, it would help the authors to identify cases for few adverse events if we knew which subjects entered the study with a "floating sensation" and which subjects
developed a "floating sensation" after the gel treatment. For subjects entering the study with the symptom, experiencing the symptom after treatment may not be associated with the treatment. For subjects without the symptom, experiencing the symptom after treatment may be associated with the gel. (Major Compulsary Revision)

4. What is the “floating sensation”? Please define clearly. Do you mean a light-headedness or dizziness? (Minor Essential Revision)

5. The term “no response” was used while the “recovery” was used for hearing improvement. I suggest to use the term “no recovery” to be consistent. (Minor Essential Revision)

6. In reference 15 under References, the year of publication is missing. (Minor Essential Revision)

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests.