Reviewer's report

Title: Comparison of the benefits of cochlear implantation versus contra-lateral routing of signal hearing aids in adult patients with single-sided deafness: study protocol for a prospective within-subject longitudinal trial

Version: 2 Date: 17 April 2014

Reviewer: Elizabeth Fitzpatrick

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Review: 'Comparison of the benefits of cochlear implantation versus contra-lateral routing of signal hearing aids in adult patients with single-sided deafness: study protocol for a prospective within-subject longitudinal trial'

1. Will the study design adequately test the hypothesis?
This report describes the protocol for a trial that is designed to evaluate whether a cochlear implant in the impaired ear provides benefit to patients with single-sided deafness who do not gain sufficient benefit from a contralateral routing of signal hearing aid system. Three endpoints are to be investigated: localization, speech recognition, and quality-of-life. The study design is well-planned to answer the primary questions.

This is an important study question for those individuals affected by single-sided deafness (SSD). Given the high cost of cochlear implantation relative to other treatments, it requires careful investigation.

2. Are sufficient details provided to allow replication of the work or comparison with related analyses: if not, what is missing?
Overall, the study protocol is well written with sufficient details to replicate the work. I have a few suggestions for details that should be added:

Minor discretionary revisions:
Background
I would recommend a little additional information on the CROS system, which is reported as standard care for single-sided deafness in the UK. Does this refer to conventional (air conduction) only or also include quasi-transcranial and transcranial bone conduction CROS systems?

Please provide reference(s) if there is evidence for the statement below to indicate that some patients with SSD who are eligible candidates for a BAHA do not choose the device: “The placement of a permanent bone-anchored abutment through the skin may also be unacceptable to some patients.”

Methods/Design.

p. 3. End of 1st paragraph, methods section. The secondary endpoints are clearly stated and it would be useful to have the primary endpoints identified briefly in this section as well, i.e., sound localisation and speech recognition.
Inclusion criteria
I found myself looking for how ‘minimal benefit from a hearing aid’ will be determined. There is a good description in the section under ‘Exclusion criteria’ which I would suggest moving to the above section when the notion is first introduced.

I wondered if any consideration has been given to prior experience with a CROS configuration or if this is an exclusion criterion.

Exclusion criteria.
It would be useful to know the duration of the trial period with amplification. Also, this section falls under ‘exclusion’ criteria but in fact these patients would qualify for the study – I suggest a subheading or slight re-organization to avoid confusion.

Minor essential revisions:
Interventions
There is no mention of rehabilitation being provided during the period of CROS system use. The post-cochlear implant intervention process is more clearly described; rehabilitation costs are covered by Cochlear Europe. It is important to know whether patients will be seen more than once with the CROS device, for example, for fine-tuning and encouragement as they would be for a cochlear implant. Given that the acceptance rate is known to be quite low for patients fit with CROS systems, there is a risk that patients will not use the device, particularly since they presumably know that they are later being fit with a cochlear implant.

The ‘practice period’ with a cochlear implant is substantially longer (approx. 8 months after speech processor fitting) than with the CROS configuration. It would be helpful if the authors could comment on the rationale for the short period. Is any period of adjustment needed for listeners to adjust to wearing a CROS system?

Please state whether the testing is administered using recorded material and if the test is BKB sentences or other test material.

3. Does the manuscript adhere to the relevant standards for reporting and data deposition: if not, in what ways?
The manuscript adheres to acceptable standards for reporting. Trial registration number is provided.

4. Is the writing acceptable?
The protocol is well-planned and clearly written.

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I have no competing interests to declare.
I look forward to the results of this interesting work.
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:
I have no competing interests.