Cochlear

PROTOCOL

Evaluation of the Baha SoundArc in Pediatric Patients

Investigation Number:
CAM5714

Version 1.0
August 18, 2017

Study Sponsor:

Cochlear Americas
13059 E. Peakview Avenue,
Centennial, CO 80111

Cochlear

Investigator Responsibilities

I, the undersigned, am responsible for the conduct of the study at the site below and by my signature below, I confirm that I have read, understand and will strictly adhere to the study protocol, “Evaluation of the Baha SoundArc in Pediatric Patients.”

Clinical Investigational Site

Primary Investigator’s Name (print)

Title

Signature

Sponsor Representative

Title

Signature

Cochlear

Table of Contents

Cochlear

1.0 Clinical Synopsis

Investigation title	Evaluation of the Baha SoundArc in Pediatric Patients
Total expected duration of the clinical investigation	4 to 6 weeks
Enrollment period	Existing subjects fitted with Baha sound processor on Softband for a minimum of three months
Expected duration per subject	Up to 6 weeks
Investigational design	The clinical investigation will be conducted as a nonrandomized, single-subject, repeated-measures design in which each subject serves as his/her own control.
Number of subjects	Up to 30 total subjects
Number of investigational sites	Up to 3 sites
Inclusion Criteria	• Existing recipients using a Baha sound processor on a Softband for at least three months • Subjects aged 5 through 12 years of age • Subjects should be able to perform clinical testing adapted for age and developmental status, (Threshold sound field audiometry and basic monosyllabic word test, PBK) • Willingness on behalf of the subject's parent or guardian to complete study questionnaire
Exclusion criteria	• Subject's inability to perform requisite test measures as described in the study protocol
Primary objective	• To evaluate patient experience when using the Baha SoundArc after a one month take-home trial, compared to the existing Baha Softband on the Participant Take Home questionnaire

Primary endpoint	• Patient experience for the Baha SoundArc will be the same or better for the majority of participants (75% or greater)
Additional analyses	• To characterize clinician satisfaction of the fitting and use of the Baha SoundArc • To characterize speech perception on the PBK word recognition test in quiet when using the Baha SoundArc after 1 month of experience • To characterize aided thresholds using the SoundArc when compared to the Baha Softband
Investigation schedule	**Visit 1:** • Description of Study to Subject or Subject's parent/guardian • Informed Consent • Measurement of Audiometric thresholds and PBK word list (1 list) with the subject's Baha Sound processor on a Softband in Sound field • Fitting and adjustment of the Baha SoundArc • Orientation and instruction for use in preparation for the take home trial **Visit 2:** • Measurement of Audiometric thresholds and PBK word list (1 list) with the subject's Baha Sound Processor on the SoundArc in Sound field • Completion of the subject/parent questionnaire on the experience of use of the Baha SoundArc using the Subject Take Home questionnaire • At the conclusion of study, clinician(s) will complete a questionnaire detailing the usability, functionality and preferences using and fitting the Baha SoundArc

Cochlear

2.0 Glossary

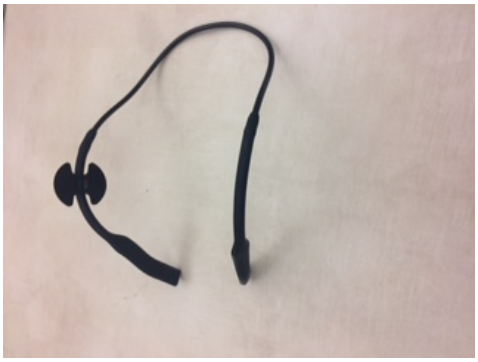
Term	Definition
AE	Adverse Event
IRB	Institutional Review Board
CRF	Case Report Form
SAE	Serious Adverse Event
PBK	Phonetically Balanced Kindergarten word list
Baha Sound Processor	Bone Conduction sound processor
Baha Softband	Non-surgical connection method for use with Baha Sound processor fitted to an elastic fitted band
Baha SoundArc	Non-surgical connection method for use with a Baha Sound processor fitted to a wire arc (behind the head), adjustable for head size and comfort
Subject Questionnaire	Questionnaire to be completed by subject or subject's parent or guardian describing the experience of Baha SoundArc use during the take-home trial
Clinician Questionnaire	Questionnaire to be completed by the fitting clinician(s) describing the usability, function and preferences using the Baha SoundArc

3.0 Introduction and background

The Baha SoundArc coupling system has been developed as a non-surgical coupling of a Baha sound processor to the skull allowing the transfer of vibrational energy to the cochlear partition via bone conduction pathways. Today we offer two alternatives to this non-surgical approach; the Baha headband/test band and the Baha Softband. Each of these current options have benefits and liabilities. In the liability column, there is comfort and cosmetic concerns to consider. In the benefits column, there is need to provide a vehicle to test a potential candidate with a bone conduction system prior to making final decisions regarding implantation of the Baha system. There is also a population (under 5 years) where a need exists for Bone conduction amplification. Current approved clearance is for children 5 years and older. This is due to less mature bone substrate and the act of osseointergration. There is also in a more limited group, a need for a non-surgical option for use of the Baha Bone conduction sound processor in candidates that cannot or will not accept a surgical implant.

Currently, persons in need of this non-surgical coupling of a Baha sound processor had only to choose between the Headband/Test Band that is a spring steel appliance that holds the vibrating Baha sound processor in contact with the skull to access the bone conduction pathway. Use of this appliance is acceptable in short-term wearing conditions but in practice is not always comfortable for long-term wear. In addition to wearing comfort, there are often cosmetic objections to wearing this appliance long-term. A more comfortable option is the Baha Softband, which is a latex-free elastic strap that contains a size adjustment buckle, a safety break-away connector and a force contact point where the Baha sound processor attaches. The original design intention of the Baha Softband was in the pediatric population. Older children and adults can also use this method of coupling. However, the Softband has a negative cosmetic appeal in this older child to adult patient pool.

Due to the cosmetic and comfort issues, the team at Cochlear Bone Anchored Solutions (CBAS) has produced the Baha SoundArc seen below.



Cochlear

3.1 Study Objective

To evaluate patient experience when using the Baha SoundArc after a one month take-home trial, compared to the existing Baha Softband on the Participant Take Home questionnaire in a group of 30 pediatric subjects.

4.0 Criteria for Subject Selection

Cochlear Americas expects to enroll up to 30 patients at up to 3 North American Baha implant centers. The duration of the multi-site study is expected to be up to 2 months, depending on subject recruitment.

4.1 Inclusion Criteria

Subjects will have been fitted with the Baha Sound processor on a Softband for a minimum of 3 months:

- Aged 5 to 12 years of age
- Subjects should be able to perform clinical testing adapted for age and developmental status (threshold sound field audiometry and basic monosyllabic word tests)
- Willingness on behalf of the subject's parent or guardian to complete study questionnaire

4.2 Exclusion Criteria

Subject's inability to perform requisite test measures as described in the study protocol

5.0 Methods and Procedures

5.1 Device description

Cochlear™ Baha sound processors to be used in this study may include commercially available Baha 3, Baha 4, or Baha 5 series processors. These devices need to have been previously fitted and worn by the subject for a minimum of three months on a Baha Softband.

5.2 Description of Test Measures

5.2.1 PBK Word Recognition Test

The PBK Word Test (Haskins, 1949) is a validated test used clinically and in research to assess the speech perception performance of individuals with hearing aids, cochlear implants, and bone anchored devices on open-set word recognition. The test consists of 4 recorded lists of 50 monosyllabic words in CD format. For this study, one list will be administered in quiet at a level equal to 60dBA in the sound field and scored as total number of words correct, which will

be expressed as a percentage correct for this study. Subjects will be tested using a configuration of speech at 0º azimuth in quiet. The non-test ear will be plugged for testing.

5.2.2 Audiometric Sound Field Threshold Test Aided

The Audiometric Sound Field Threshold Test will be carried out using narrow band noise stimuli at audiometric frequencies, 250Hz, 500Hz, 1000Hz, 2000Hz, 3000Hz, and 4000Hz using standard methods for threshold measurement that may be adapted for age and developmental level. The non-test ear will be plugged.

5.2.3 Unscheduled Visit

If a subject requires an interim clinical visit, an Unscheduled Visit Form will be completed. Information collected will include reason for visit, activities completed and visit date.

5.3 Summary of Data Collection Visits

5.3.1 Visit 1:

- Description of Study to Subject or Subject's parent/guardian
- Informed Consent
- Measurement of Audiometric thresholds and PBK word list (1 list) with the subject's Baha Sound processor on a Softband fitting in Sound field
- Fitting and adjustment of the Baha SoundArc
- Orientation and instruction for use in preparation for the take-home trial

5.3.2 Visit 2:

- Measurement of Audiometric thresholds and PBK word list (1 list) with the subject's Baha Sound Processor on the SoundArc in Sound field
- Completion of the subject/parent questionnaire on the experience of use of the Baha SoundArc using the Subject Take Home questionnaire
- At the conclusion of study, clinician(s) will complete a questionnaire detailing the usability, functionality and preferences using and fitting the Baha SoundArc

5.4 Data Analyses

5.4.1 Sample Size

Thirty pediatric subjects will be consented to participate in this study across 3 large pediatric centers.

5.4.2 Missing Data

All efforts will be put forth to ensure near complete follow-up, with particular focus on the assessment of the primary outcome and occurrence of adverse events. Regular reminders of subject follow-up due dates will be provided to participating centers to facilitate scheduling of follow-up visits.

Cochlear

5.4.3 Access to Study Documents and Data Monitoring

Investigator(s) will provide access to study documentation including source data for the purposes of monitoring, audits, IRB review, and regulatory inspections.

The Sponsor will designate appropriately trained monitors to review the progress of this study and assure the quality and integrity of data accumulated. Clinical monitors, as representatives of the Sponsor, have the obligation to provide site qualification and initiation visits as well as regular site visits. The study monitors will be employees of the Sponsor, Cochlear Americas, or any contracted vendors qualified by experience and training to conduct study site monitoring for this investigation. Study monitors, employed by Cochlear Americas, for this study will be:

Lori O'Neill, AuD
Cochlear Americas
13059 E. Peakview Ave.
Centennial, CO 80111

Aaron Parkinson, PhD
Cochlear Americas
13059 E. Peakview Ave.
Centennial, CO 80111

Kimberly Nix, AuD
Cochlear Americas
13059 E. Peakview Ave.
Centennial, CO 80111

Megan Mears, AuD
Cochlear Americas
13059 E. Peakview Ave.
Centennial, CO 80111

Shanell Laner
Cochlear Americas
13059 E. Peakview Ave.
Centennial, CO 80111

Heather Ottum
Cochlear Americas
13059 E. Peakview Ave.
Centennial, CO 80111

Ginger Grant, AuD
Cochlear Americas
13059 E. Peakview Ave.
Centennial, CO 8011

All data generated during this study and the source documents from which they originated are open to inspection by the Sponsor or its representative, and other regulatory agencies. Upon completion of the study, the clinical monitor will conduct a final visit, or close-out of the site. The objectives of this visit are to ascertain that all subjects are accounted for, that the regulatory records and reports are complete, verify that study device and other supplies have been accounted for and ensure that the Investigator is aware of his/her responsibilities post-study.

Cochlear

5.5 Data Storage and Confidentiality

5.5.1 Confidentiality

A Case Report Form (CRF) will be completed for each study subject, summarizing all clinical and study data. The CRF contains confidential material. Subjects will only be referred to in the CRF by their subject numbers in order to retain subject confidentiality. Specific instructions to complete the CRF shall be provided to the clinical investigation team as appropriate.

Copies of the completed CRFs are to be provided to the Sponsor as soon as practical after completion and review. The original CRFs are to be retained by the Investigator for a period of time as determined by local regulations.

5.5.2 Subject Identification

To maintain confidentiality, the subject's name will not be recorded on any study document other than the informed consent form. All individuals who provide informed consent (sign the informed consent form) are considered consented into the study and will be assigned a unique identifier. A unique alphanumeric code will identify the subject throughout the course of the study. For example, US01-ARC-0000, where:

- US = United States
- 01 = a sequential numeral corresponding the order in which a subject is enrolled into the study for a given study site, in this case this would correspond to the first subject recruited into the study for a particular site,
- ARC = an abbreviation for the study, in this case "ARC" for the Baha SoundArc,
- 0000 = a unique, numeric study site identification.

5.5.3 Release of Medical Information

Subjects will be required to release the exchange of medical information between the Investigator(s) and the Sponsor. This requirement will be clearly identified in the Informed Consent form.

6.0 Risk Benefit Statement

It is possible but not guaranteed that advances in Baha technology will improve performance via use of the Baha SoundArc. This clinical investigation will help to inform the future development of associated clinical guidance when fitting Baha patients.

6.1 Risk Category

As determined by the Sponsor, this study has been designated as non-significant risk. The Baha Softband/SoundArc, and sound processor used in this study are commercially cleared by the Food and Drug Administration (FDA) and is considered standard of care.

Cochlear

6.2 Potential Risk and Protection against Risks

Subjects may experience discomfort while using the Baha SoundArc. This could include, pressure at the temple piece, rash or itching. These issues are usually resolved by adjustment of the position and tension of the SoundArc bow.

6.3 Potential Benefits to Subjects

Potential benefits to subjects may include improved wearing experience when using the Baha SoundArc. It cannot be promised that subjects will receive any medical benefits from participating in this study.

6.4 Alternatives to Participation

In lieu of study participation, patients may elect to continue standard clinical care and use of their Baha Sound Processor on the Baha Softband.

7.0 Subject identification, Recruitment, and Consent/Assent

7.1 Method of Subject Identification and Recruitment

Subjects will be recruited into the study sequentially to ensure a subject pool representative of the general population of those with hearing loss, with no pre-selection based on age (other than being between 5 and 12 years-of-age), ethnicity or gender as described in Section 2.0. The identification and recruitment of subjects will protect patient privacy and be free of undue influence.

7.2 Process of Consent

Prior to recruitment of any subjects into the study, written approval of the investigational plan including clinical protocol and informed consent form will be obtained from reviewing Institutional Review Board (IRB). An interview (as part of the informed consent process) will be conducted by the surgeon and/or audiologist to inform the subject about rationale for and the details, aims, objectives of the study, study expectations, evaluation schedule, and the risks and benefits of the trial treatment (and alternative treatments), and the extent of the patient's involvement. Written informed consent shall be obtained from each subject after this explanation. After reviewing the Informed Consent Form, the subject will be given the opportunity to review and ask questions about the Informed Consent Form and/or the study prior to signing the Informed Consent Form. The subject will be offered the opportunity to take the form home to discuss with family members should they choose to do so. If they sign the Informed Consent Form, the subject twill then be given a copy of the signed Informed Consent Form to take home.

The Investigator is responsible for ensuring that all patients give written informed consent prior to any study-related examination or activity. All patients shall sign and date the Informed Consent Form, and a copy of the Informed Consent Form shall be given to the patient. The Sponsor and the Investigator(s) shall avoid improper influence on or inducement of the subject, monitor, the Investigator(s) or other parties participating in or contributing to the clinical investigation.

7.3 Subject Capacity

Subjects participating in this study will have the capacity to provide informed consent as assessed by the Investigators. The only anticipated exception this is minors, for which assent will be obtained in addition to parental consent.

7.4 Subject/Representative Comprehension

7.5 Consent Forms

The informed consent form provided for this study will meet requirements for specific sections as described in 21 CRF 50.25.

7.6 Documentation of Consent

A subject is not considered enrolled until a properly executed Informed Consent Form has been obtained and inclusion/exclusion information has been reviewed and approved by Cochlear Americas, as evidenced by the return of a study approval form signed by a Cochlear Americas representative.

7.7 Costs to the Subject

There will be no cost to the study subjects participating in this study.

7.8 Payment for Participation

Subjects will be paid $12.50/hour for study visits completed. If a subject withdraws from the study before completing all study visits, they will be compensated $12.50/hour for the study visits which were completed. In order to receive payment for participation, subjects will need to complete a W-9 form, which is required because study payments for time are taxable.

Subjects will be paid for transportation to and from the study visits at a rate of .52 cents per mile from home to visit and return. Reimbursement for parking on the day of the study visit will also be provided.

7.9 Institutional Review Board

Each site will obtain approval from its designated IRB prior to commencing any study-related activities. A copy of the IRB approval will be kept in the Investigator file(s). Any additional requirements imposed by the IRB and/or regulatory authority shall be followed. The Investigator(s) will submit the appropriate documentation if any necessary extension or renewal of the IRB approval must be obtained.

Study procedures will not be changed without mutual agreement between the Sponsor and the Investigator(s). Changes will be implemented in a signed protocol amendment, and for significant changes, approval will be obtained from the IRB.

Cochlear

8.0 References

Haskins, H. A., (1949) A phonetically balanced test of speech discrimination for children, Unpublished master's thesis. Northwestern University, Evanston, IL, USA.