Post-market clinical follow-up of a magnetic bone conduction implant (Cochlear Baha® Attract System)

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This post-market clinical follow-up investigation aims to evaluate the usability and the mid- to long-term performance of the Baha Attract System in terms of hearing outcomes and safety. The objective is to compare the hearing performance with the...

Ethical review	Approved WMO
Status	Pending
Health condition type	Hearing disorders
Study type	Observational non invasive

Summary

ID

NL-OMON41439

Source
ToetsingOnline

Brief title
Cochlear

Condition

- Hearing disorders

Synonym
Conductive or mixed hearing loss or single-sided sensorineural deafness (SSD):

Research involving
Human

Sponsors and support

Primary sponsor: Cochlear Bone Anchored Solutions AB
Source(s) of monetary or material Support: Cochlear Bone Anchored Solutions AB

Intervention

Keyword: Bone conduction implant, Hearing aid, Hearing implant

Outcome measures

Primary outcome

To compare the hearing performance with the Baha Attract System (aided) and the unaided hearing performance.

Secondary outcome

•*To compare the hearing performance with the Baha Attract System and the hearing performance with the same sound processor on a Baha Softband.

•*To compare health status and health-related quality of life and utility scores before and after use of the Baha Attract System.

•*To compare self-reported assessment of hearing aid outcome before and after use of the Baha Attract System.

•*To collect surgical information.

•*To investigate if the Sound Processor Magnet strength and magnetic force required for retention changes over time.

•*To collect information regarding pain, discomfort, numbness and soft tissue status.

•*To monitor implant survival.

•*To collect Adverse Events and device deficiencies.

Study description

Background summary

Bone conduction implants such as the Baha® system were first clinically described in 1977 by
Tjellström et al.1, and since then more than 100.000 patients have been treated with this technique.
The traditional Baha system consists of a titanium implant, which connects to a sound processor via a
skin-penetrating abutment. The sound processor transforms sound into vibrations that are transmitted
via the abutment and titanium implant to the skull bone and then to the cochlea. Although Baha
treatment has been proven to be a safe and effective treatment for patients with a mixed or conductive
hearing loss or single-sided sensorineural deafness, a large proportion of Baha candidates refuse to
undergo Baha surgery, mainly due to aesthetic concerns related to the percutaneous abutment. Other
candidates may not be suitable for a percutaneous Baha due to being - for medical reasons or other -
unable to perform the daily cleaning that the percutaneous abutment requires.
This clinical investigation will assess the usability and clinical performance of a magnetic bone conduction implant, Cochlear**Baha**Attract System. The device aims to reduce the perceived barriers for Baha candidates by providing a non-skin penetrating bone anchored hearing device. This gives Baha candidates a treatment option with improved cosmetic outcomes and minimal aftercare. In the Baha Attract System, the sound processor connects to a nonpercutaneous implant through a transcutaneous coupling. The transcutaneous coupling consists of an implanted magnet, which is fixated to the osseointegrating titanium implant underneath the soft tissues, and an external magnet placed on top of the skin. The sound processor attaches to the external magnet via a snap coupling. The transducer of the sound processor transforms sound into vibrations which are conducted through the soft tissues and via the titanium implant to the skull and onwards to the cochlea.

The Baha Attract System is CE-marked and has been in clinical use in Europe since September 2013,
and received FDA clearance in the US in November 2013.

The Baha Attract System is intended for patients (adults and children) with conductive or mixed hearing loss or single-sided sensorineural deafness. Patients should have sufficient bone quality and quantity to support successful implant placement.

While the Baha Attract System is approved for use in both adults and children, this investigation is
limited to adult subjects. The paediatric population constitutes an inhomogeneous patient group (agerelated), and currently there are no

audiological tests that are suitable for comparisons across age ranges and across multiple countries/languages. Performance evaluation of the Baha Attract System in children should be performed as separate investigations.

The rationale behind this post-market clinical follow-up investigation is to collect data regarding the usability and clinical performance of the Baha Attract System in subjects with hearing impairment that are candidates for Baha surgery:
•*to evaluate the efficacy of the Baha Attract System in terms of hearing performance compared to the unaided situation and compared to a pre-operative test situation using the sound processor on a Baha Softband;
•*to evaluate the mid- and long-term safety of the Baha Attract System.

This investigation is expected to demonstrate that the Baha Attract System performs within its intended use and is a suitable treatment for patients with a conductive or mixed hearing loss or single sided sensorineural deafness.

Study objective

This post-market clinical follow-up investigation aims to evaluate the usability and the mid- to long-term performance of the Baha Attract System in terms of hearing outcomes and safety. The objective is to compare the hearing performance with the Baha Attract System (aided) and the unaided hearing performance.
The investigation will also provide input to future product developments in the area of transcutaneous bone conduction hearing.

Study design

The investigation is designed as an international multicentre, open, prospective clinical investigation. The investigation comprises a 6-month investigation with an additional 18-month follow-up period. The investigation will be performed in an open design, since it is not possible to perform the investigation in a blinded fashion. The main evaluations of the investigation, i.e. free-field hearing tests, are relevant and objective methods.

Study burden and risks

As with any surgical products, there is a risk that unanticipated Adverse Events may occur. The subjects will be closely monitored in the investigation and instructed to contact the responsible investigator if they experience any untoward effect.

Risks associated with the transcutaneous coupling that cannot be completely eliminated include
magnetic retention difficulties, pressure-related skin complications and pain/discomfort. The system
has been designed to minimise these risks. Tests have demonstrated that the Implant Magnet in combination with the BI300 Implant is MRI conditional for up to 1.5 Tesla. Subjects that receive the Baha Attract System will receive an MRI card, for use by radiologists to evaluate and plan any MRI examination.

Subjects that have received radiation therapy at the same side of the skull where the Baha Attract will be positioned are excluded from the investigation. Participation in the investigation requires slightly more frequent follow-up visits for the subject than what is normally required, and the duration of the visits will be slightly longer than normal. After surgery subjects are asked to return to the hospital for 7 follow up visits (day 10, week 4, 6, 12, month 6, 12 and 24). The more frequent visits will provide the subject the opportunity to more frequently interact with the treating physician.

With the Baha Attract System, the subjects will be able to benefit from the Baha sound processor without an abutment penetrating the skin, thus providing cosmetic advantages compared to a traditional Baha. In addition, with the Baha Attract System, there is reduced need for daily cleaning to maintain a healthy implant site compared to a percutaneous Baha, and risk of adverse tissue reactions related to the percutaneous passage are eliminated.

It is expected that the audiological performance of the Baha Attract System will be similar to, or somewhat better than, Baha on a Softband. The performance in the high frequency range are likely to be slightly lower for subjects with the Baha Attract System compared to the percutaneous solution, due to transcutaneous attenuation of the vibrations through the skin.

Subjects will receive compensation for travelling expenses made for extra visits to the clinic.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Adult subject, i.e. >= 18 years of age
• Conductive or mixed hearing loss in the ear to be implanted:
Bone conduction thresholds with a pure tone average PTA4 of < 30 dB hearing level (mean of 500, 1000, 2000 and 4000 Hz).
OR
Single-sided sensorineural deafness (SSD):
o European sites: Bone conduction thresholds with a pure tone average PTA4 of < 30dB hearing level (mean of 500, 1000, 2000 and 4000 Hz) in the good ear.
o US sites: Air conduction thresholds with a pure tone average PTA4 of <= 20 dB hearing level (mean of 500, 1000, 2000 and 3000 Hz) in the good ear OR Subject is indicated for an AC CROS but*for some reason*cannot or will not use an AC CROS.
• No previous bone conduction implant on the side of the skull to be implanted.
• Signed informed consent.

Exclusion criteria

• Subjects that are scheduled for simultaneous bilateral implant surgery. The investigation is limited to subjects with unilateral use of the Baha Attract System (however, bilateral hearing loss is not an exclusion criterion).
• Suitable implant position for the BI300 Implant (4 mm or 3 mm) not found during surgery due to insufficient bone quality and/or bone thickness.
• Less than 3 mm soft tissue thickness at the planned implant site.
• Subjects that have received radiation therapy at the same side of the skull where the Baha

Attract System will be positioned.
• Condition that could jeopardise osseointegration and/or wound healing as judged by the investigator (e.g. osteoporosis, psoriasis, use of corticosteroids).
• Uncontrolled diabetes as judged by the investigator.
• Condition that may have an impact on the outcome of the investigation as judged by the investigator.
• Unable to follow investigational procedures (e.g. to complete quality of life scales).
• Participation in another investigation with pharmaceuticals and/or medical device.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2014
Enrollment:	25
Type:	Anticipated

Medical products/devices used

Generic name:	Cochlear Baha Attract System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	27-02-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	06-05-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-02-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-01-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-02-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL47585.091.13