# Benefits of the HiResolutionTM Bionic Ear System in Adults with Low-Frequency Hearing.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Hearing disorders |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON41455

**Source**
ToetsingOnline

**Brief title**
AB-RCA-01-13

### Condition

- Hearing disorders

**Synonym**
mild to severe deafness

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Advanced Bionics Corporation
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Preservation benefit residual hearing

## Outcome measures

**Primary outcome**

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Primary Study Objectives

To demonstrate that free field word recognition scores in quiet and noise with CI *ON* are significantly better than the best aided pre-implant scores in the ear to be implanted (contralateral ear plugged) after 12 months of implant use.

Primary Endpoint

CI aided free field word recognition scores in quiet and noise after 12 months of implant use are significantly better than the best aided pre-implant baseline scores in the to be implanted ear (contralateral ear plugged).

Primary Evaluation

To demonstrate that word recognition scores in the implanted ear are significantly higher than scores at baseline with conventional amplification in the to be implanted ear. The null and alternate hypotheses to be tested are:

H0: mu <= 0 versus H1: mu > 0

where mu is the mean of the difference for words in quiet.

Primary PMCF objective

All adverse events will be tracked and reported after being adjudicated by a Data Safety Monitoring Board (DSMB) to evaluate whether there are adverse events related to the HiResolution system to be.

**Secondary outcome**

Additional Interest

Evaluate the ability to preserve functional residual hearing after implantation with the HiFocus MS electrodes in adults with mild -to-moderate low-frequency hearing loss during the first 12 months of CI use.

Additional Evaluation

Classification of the preservation of residual hearing based on the unaided acoustic hearing thresholds measured at 1, 3, 6 and 12 months (under earphones) in the implanted ear as compared to the unaided pre-implant thresholds in the same ear for audiometric frequencies 125, 250, 500, 750 and 1000 Hz. Threshold changes from baseline will be calculated for each frequency separately and for a low-frequency pure-tone average (LF-PTA = average of 125, 250, 500 and 750 Hz).

Individual-frequencies and LF-PTA results will be classified as follows:

• Near complete preservation of hearing: threshold shift <= 15 dB

• Moderate preservation of hearing: 16 dB < threshold shift <= 30 dB HL

• Marginal preservation of hearing: 30 dB < threshold shift <= 50 dB HL

• No preservation of hearing: threshold shift > 50

Results to be divide between pure round window and insertion after extended round window/cochleostomy.

Further initiatives

• Full analysis at 3, 6 and 12 months follow up after device activation.

• LF-PTA results to be divide between insertion via pure round window ,

extended round window or cochleostomy.

• To demonstrate that aided sentence-in-quiet and noise scores in the implanted

ear are significantly higher than aided scores at baseline with best aided

conventional amplification in the to be implanted ear.

• To evaluate acoustic only residual hearing during the first 12 months of

implant use

• Evaluate effect of the surgical procedure on residual hearing

• Health Utilities Index 3 questionnaire at baseline and 3 months post

activation

## Study description

**Background summary**

The goal of this investigation is to generate the needed PMCF data for the electrode. As a point of interest we would like to evaluate the benefit to patients with low-frequency residual hearing implanted with the HiFocus Mid-Scala Electrode. The HiFocus Mid-Scala electrode array is designed to allow surgeons the flexibility to use a variety of contemporary surgical techniques that have been shown to enable easy insertion and to minimize cochlear trauma (see, e.g., Adunka and Buchman, 2007; Friedland and Runge-Samuelson, 2009; Roland et al., 2007). Temporal bone experiments have shown the HiFocus Mid-Scala electrode array to be straightforward to insert while causing minimal trauma to cochlear structures during and after surgery (Lenarz et al., 2010). In addition , the HiFocus Mid-Scala has already shown to be a safe electrode and promising post op clinical results in the premarketing study that is now in the final stage. Because the advantages of the HiFocus Mid-Scala electrode array are expected to be related to surgical technique, hearing benefits experienced by recipients have been shown to be similar to benefits associated with previous electrode arrays. This has also been substantiated by

computational modeling (Frijns et al., 2010).

**Study objective**

The primary objective of this study is to demonstrate that free field word recognition scores in quiet and noise with CI *ON* are significantly better than the best aided pre-implant scores in the ear to be implanted (contralateral ear plugged) after 12 months of implant use.

**Study design**

Non-randomized , prospective , observational , within-subjects repeated-measures design where each subject serves as his/her own control.

NEW:
Advanced Bionics in collaboration with Phonak has developed an EAS compatible sound processor type Naída CI Q90 EAS (Figure 1) which will receive CE marking in the next days.

Arm 1: Implanted subjects with ipsilateral unaided hearing loss of 90 dB or more at: 250 Hz, 500 Hz or 750 Hz will remain fitted with the electronic stimulation set-up and the Naída Q70.

Arm 2: Implanted subjects with ipsilateral unaided hearing loss of less than 90 dB at: 250 Hz, 500 Hz or 750 Hz will receive the Naída CI Q90 EAS that will be fitted with the EAS functionality *on*. These subjects will have 1 additional speech perception test at the time of exchanging the sound processors. A first standard test with the Naída Q70 and a second similar one with the Naída CI Q90 EAS.

Arm 3: all newly enrolled subjects will be directly fitted with the Naída CI Q90 EAS with the EAS functionality *on* or *off* per the criteria of Arm 1 or 2.

**Study burden and risks**

There might be some additional word or sentence test to be performed.

# 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

•18 years of age or older
•Definite Postlingual onset of severe-to-profound hearing loss as documented by completing main stream primary education
•Preferably, aided mono- or bisyllabic word score of >= 15 % at 65 dB SPL in quiet in the ear to be implanted
•Local language proficiency
•Bilateral, sensorineural hearing loss of a mild to moderate degree in the low frequencies and a severe or a greater degree of hearing loss in the mid-to-high frequencies, defined as pure-tone thresholds (PT):
- PT <= 60 dB HL at 250, 500, and 750 Hz BUT at one of these 3 frequencies a value <= 70 dB is acceptable
- PT >= 70 dB HL at 2000, 4000, and 8000 Hz
•Contralateral ear PTA ± 30 dB HL at 250, 500, 750 and 1000 Hz as compared to the ear to be implanted

## Exclusion criteria

•Previous inner or major middle ear surgery or active middle ear pathology.

•Cochlear malformation or obstruction as confirmed by pre OP MRI (an MRI is required to exclude obstruction when history indicates a higher risk for obstructions)
•Presence of additional disabilities that would prevent or interfere with participation in the required study procedures
•Medical or psychological conditions that contraindicate surgery or impact the ability to manage an implanted device or the study-related procedures
•Evidence of central auditory lesion or compromised auditory nerve
•Concurrent participation in other study

# Study design

## Design

| | |
|---|---|
| Study phase: | 4 |
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Other |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 25-11-2013 |
| Enrollment: | 12 |
| Type: | Actual |

# Ethics review

Approved WMO

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| Date: | 24-09-2013 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

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| Approved WMO Date: | 22-05-2014 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

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| Approved WMO Date: | 15-07-2015 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

# 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 |
|---|---|
| Other | clinicaltrials.gov |
| CCMO | NL43799.058.13 |