Evaluation of the safety and efficacy of the HiFocus V electrode array in adults with severe-to-profound hearing loss through analysis of post-implant benefits of the HarmonyTM HiResolutionTM Bionic Ear cochlear implant system

Published: 12-09-2011
Last updated: 29-04-2024

Sectie 2 van het CIP

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

Summary

ID

NL-OMON35760

Source
ToetsingOnline

Brief title
HiFocus_V

Condition

- Hearing disorders

Synonym
deafness, severe-to-profound hearing loss

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cochlea, Electrode, HiFocus_V

Outcome measures

Primary outcome

Section 2.2 van het CIP

Secondary outcome

Section 2.2 van het CIP

Study description

Background summary

Sectie 1 van het CIP

Study objective

Sectie 2 van het CIP

Study design

Sectie 2 van het CIP

Study burden and risks

There might be minimal additional word and sentence testing performed.
Burden has been reduced to an ablolute minimum
In Section 3 of the CIP risks are described in detail.

Contacts

Public
Advanced Bionics Corporation

Laubisrütistrasse 28
8712 Stäfa
CH
Scientific
Advanced Bionics Corporation

Laubisrütistrasse 28
8712 Stäfa
CH

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* * 18 years of age
* Postlingual onset of severe-to-profound hearing loss (* 4 years of age)
* Sensorineural hearing loss of severe or greater degree in both ears, defined as a pure-tone average (PTA: 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz) of * 70 dB HL
* Marginal hearing aid benefit with appropriately fitted hearing aids, defined as a monosyllabic word score in quiet of * 50% in the best-aided condition
* Proficient in the local language of the investigational center
* Willingness to participate in all scheduled procedures outlined in the protocol

Exclusion criteria

* Cochlear malformation or obstruction that would preclude adequate insertion of electrode array
* 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 to participate in the study related procedures
* Evidence of central auditory lesion or compromised auditory nerve
* Pregnancy at time of surgery (responsibility of the hospital)

Study design

Design

Study phase:	3
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-06-2012
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	HarmonyTM HiResolutionTM Bionic Ear cochlear implant system
Registration:	No

Ethics review

Approved WMO

Date:	12-09-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	18-07-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	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	BFARM, EudraCT: 2011-002572-16
CCMO	NL37209.058.11