Bimodal and Hybrid Cochlear Implant Fitting.

Published: 11-09-2012
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In this research, psychofysical tests will be used to explore in which way the signal processing in CI and hearing aid can be optimized to fully exploit both input modalities in speech understanding, and in sound localization..

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Interventional

Summary

ID

NL-OMON37401

Source
ToetsingOnline

Brief title
Bimodal and Hybrid Cochlear Implant Fitting.

Condition

- Inner ear and VIIIth cranial nerve disorders

Synonym
Deafness, hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Advanced Bionics European Research Centre

Intervention

Keyword: Cochleair implant, Deafness, Hearing aid, Hearing aid fitting

Outcome measures

Primary outcome

Speech understanding, sound localization.

Secondary outcome

Satisfaction

Study description

Background summary

Users of a cochlear implant increasingly have residual hearing and wear a conventional hearing aid in the non-implanted ear. Often, the acoustical and electrical input are complimentary, but in some patients a conflict arises and the hearing aid is abandoned. The reason for this conflict is unknown.

Study objective

In this research, psychofysical tests will be used to explore in which way the signal processing in CI and hearing aid can be optimized to fully exploit both input modalities in speech understanding, and in sound localization..

Study design

Interventional within subject cross-over design

Intervention

Fitting of a hearing aid.

Study burden and risks

Visits to the research facility, auditory tests for about 2 hours per visit, questionnaires.

Acclimitization to a new hearing aid: (temporary) drop of sound quality, speech

understanding, orientation in the environment - note that subjects still have their old hearing aid, if needed.

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 age.
At least 6 months of use of an Advanced Bionics CI in one ear.
Profitable residual hearing in the other ear.
Postlingual deafness.
Willingness to test a new hearing aid and participate in multiple fitting and test sessions.

Exclusion criteria

Outer, middle and inner ear problems precluding the use of a hearing aid (such as infections, vestibular reactions to sound).
Severe tinnitus.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-12-2012
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Hearing aid
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	11-09-2012
Application type:	First submission
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	NL40327.091.12