Key contributors to successful bimodal fitting

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

Summary

ID

NL-OMON39736

Source
ToetsingOnline

Brief title
Bimodal success

Condition

- Hearing disorders

Synonym
deafness, profound sensorineural hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Advanced Bionics Corporation,fabrikant CI: Advanced Bionics

Intervention

Keyword: bimodal benefit, bimodal fitting, cochlear implant, hearing aid

Outcome measures

Primary outcome

The primary study parameter is the degree of bimodal benefit. This is the benefit of wearing a CI in combination with a contralateral hearing aid (bimodal listening) in comparison to only wearing a unilateral CI. Speech understanding in difficult listening situations is still a main challenge for hearing impaired and CI patients in daily life. Therefore speech understanding in noise is considered to be the primary outcome of bimodal benefit.

- In part (A) the degree of bimodal benefit will be subjectively assessed using two daily-life disability questionnaires (SSQ and AVETA).

- In part (B) the benefit of bimodal listening will be objectively measured on speech understanding in quiet (CNC-score), spatial speech understanding in noise (SSPINtest), listening effort (VAS-test) and the ability to localize sounds (localization test).

See also: Research protocol: 7.1 Study parameters/endpoints.

Secondary outcome

- In part (A) the secondary parameters are the qualitative experiences of CI-patients with or without a contralateral hearing aid, namely in the field of hearing aid use (bimodal questionnaire) and sound quality (sound quality

questionnaire). Part (A) will also measure quality of life in this group of bimodal and unilateral CI-patients by the use of a hearing specific questionnaire (HHQ) and a general health questionnaire (HUI 3).

- Part (B) of the study focuses on the identification of more objective-technical factors influencing the degree of bimodal success. Expected contributors to bimodal benefit are residual hearing, device fitting, loudness, spectral-, temporal information and cognition. Therefore multiple secondary parameters will be measured in these fields.

See also: Research protocol: 7.1 Study parameters/endpoints

Study description

Background summary

Since the 1990s, cochlear implantation (CI) has been the standard practice to restore hearing in severely hearing-impaired and deaf patients by providing multi-channel electrical stimulation to the auditory nerve. Current reimbursement regulations in the Netherlands only allow standard unilateral implantation. However, there is a growing interest in bilateral cochlear implantation and in the benefits of binaural hearing (hearing with two ears) in general. One way of providing binaural cues to unilateral CI recipients is to wear an acoustic hearing aid in the contralateral non-implanted ear, known as bimodal hearing.
The benefits of bimodal input (e. g. speech perception in noise, localisation, listening effort) can objectively be demonstrated in clinical research settings. However, in daily practice there are often patients who choose not to wear their hearing aid (anymore) after receiving a CI in the other ear. Why this is and how this can be improved is still an unanswered but very relevant question in fitting and advising these patients in clinical practice.

See also: Research protocol: 1. Introduction and Rationale

Study objective

This research project has 2 main goals and can therefore be divided into 2 parts:

- The aim of part (A) is to qualitatively and quantitatively assess the daily-life experiences of CI-patients who do or do not wear a contralateral hearing aid. Assessing the subjective experiences of these patients is a research area that hasn*t been covered in literature yet.

- The aim of part (B) is to identify the key contributors to successful bimodal fitting. There is still little known about the reasons why patients may or may not experience benefit from wearing a contralateral hearing aid.

After the assessment of these key contributors to bimodal success, a protocol will be developed that may result in a faster and better bimodal fitting. In future research these new insights may lead to clinical tools to create more successful bimodal users with improved hearing performance. Moreover, the results from this study will probably broaden the inclusion criteria for CI in combination with HA, making it available for a larger population of patients.

See also: Research protocol: 2. Objectives

Study design

- In the first part of this study (A), unilateral CI-users will be asked to fill out a set of relevant daily-life questionnaires in the field of hearing experiences, sound quality and general quality of life. In this way their subjective experiences with wearing or not wearing a hearing aid in the contralateral ear will be reviewed.

- In the second part of this study (B), the subset of bimodal users will be asked to partake in objective testing. The aim of this part is to investigate correlations between the benefit of their bimodal fitting (e.g. speech-in-noise and listening effort) and influencing factors (e.g. residual hearing, device fitting, spectral- and temporal resolution and overlap, loudness balance and cognitive skills).

See also: Research protocol: 3. Study design

Study burden and risks

Subjects participating in this study will be asked to fill out a set of questionnaires (A) and/or perform audiological-specific tests (B). Study

associated risks are thought of as non-existent since this is an observational study with non-invasive or low impact tests and no direct interventions. Participation however takes time and effort from subjects: (A) 90 min questionnaires, (B) ca 2.5 hours testing per visit, with a total of 2 visits.

The aim of the study is to identify key contributors to bimodal success. One may expect that based on these results the clinical practice of unilateral CI patients can be improved, both on an individual and on a group basis. The clinical goal is to enable patients to successfully use CI and HA together, receiving optimal benefit from their residual auditory abilities.

See also: Research protocol: 10.4 Benefits and risks assessment, group relatedness

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

- capacitated adult (>18 years of age)
- patient of CI-team South-East Netherlands
- user of a unilateral cochlear implant (CI) of the brand Advanced Bionics (AB)
- first fit CI >= one year ago
- wearing CI speech processor (almost) always (i.e. >=10 hours a day)
Part (A):
- willing and able to fill out questionnaires
- agreed to participate in this part of the study (by returning questionnaires)
Part (B):
- wearing a contralateral hearing aid >50% of the time (>=5 hours a day)
- willing and able to visit the azM and participate in testing
- agreed to participate in this part of the study (by informed consent)

Exclusion criteria

- non Dutch speaking
- < 18 years of age or incapacitated
- bilateral cochlear implant user (CI+CI)
Part (B), concerning Cone Beam CT-scan:
- pregnancy
- claustrophobia
- inability to sit still for longer than 30sec

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-04-2013

Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	27-03-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21746
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL42011.068.13
OMON	NL-OMON21746

Study results

Date completed:	11-07-2014
Actual enrolment:	48