Bimodal success.

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21746

Source
Nationaal Trial Register

Health condition

cochlear implant
CI
cochleair implantaat
hearing aid
hoortoestel
hoorapparaat
bimodal fitting
bimodale aanpassing
bimodal benefit
bimodale winst

Sponsors and support

Primary sponsor: Maastricht Univercity Medical Centre (MUMC+)

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Source(s) of monetary or material Support: Maastricht Univercity Medical Centre (MUMC+)

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Intervention

Outcome measures

Primary outcome

The primary study parameter is the degree of bimodal benefit (=the benefit of wearing a CI in combination with a contralateral hearing aid in comparison to only wearing a unilateral CI). Speech understanding in noise is considered to be the primary outcome measure of bimodal benefit.

In part A this will subjectively be measured using two daily-life disability questionnaires.

In Part B the degree of bimodal benefit will objectively be measured on a spatial speech understanding in noise test.

Secondary outcome

In part A secondary parameters are measured by questionnaires in the field of quality of life, bimodal hearing aid use and sound quality.

In part B multiple secondary parameters will be measured in the fields of residual hearing, device fitting, loudness, spectral-, temporal information and cognition as to identify factors influencing the degree of bimodal success.

Study description

Background summary

Rationale:

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.

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.

Study population:

This study focuses on severely hearing impaired adults who use a unilateral cochlear implant with or without a contralateral hearing aid (total n=70).

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).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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.

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.

Study objective

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.

The hypothesis of this study is that more insight into the subjective experiences of these patients and the factors underlying bimodal benefit will help in developing bimodal fitting guidelines.

Study design

N/A

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. Capacitated adult (>18 years of age);

2. Patient of CI-team South-East Netherlands;

3. User of a unilateral cochlear implant (CI) of the brand Advanced Bionics;

4. First fit of CI >= one year ago;

5. Wearing CI speech processor (almost) always (i.e. >=10 hours a day);

6. Agreed to participate in the study (informed consent);

7. PART A: Willing and able to fill out questionnaires;

8. PART B: Wearing a contralateral hearing aid >50% of the time (>=5hours a day);

9. PART B: Willing and able to visit the azM and participate in testing.

Exclusion criteria

1. Non Dutch speaking;

2. <18 years of age or incapacitated;

3. Bilateral cochlear implant user (CI+CI);

4. PART B concerning CBCT-scan: Pregnancy, claustrophobia, inability to sit still for longer than 30sec.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	08-04-2013
Enrollment:	70
Type:	Unknown

Ethics review

Positive opinion

Date:	03-04-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39736
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3746
NTR-old	NTR3932
CCMO	NL42011.068.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39736

Study results

Summary results
N/A