Cochlear Implantation in subjects with asymmetrical hearing loss

Published: 13-08-2012
Last updated: 26-04-2024

1. To determine the benefit of a CI in the functionally deaf ear of patients with asymmetrical hearing loss with moderate to severe hearing loss in their best ear in terms of speech performance (in quiet and noise) and localization 2. To determine...

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

Summary

ID

NL-OMON37728

Source
ToetsingOnline

Brief title
CI asymmetric HL

Condition

- Hearing disorders

Synonym
Hearing loss, no hearing

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Advanced Bionics AG;Sta□fa;Switzerland,Advanced Bionics Corporation

Intervention

Keyword: Cochlear Implantation, Hearing loss, Quality of Life

Outcome measures

Primary outcome

1.

To determine the benefit of a CI in the functionally deaf ear of patients with

asymmetrical hearing loss with moderate to severe hearing loss in their best

ear

in terms of speech performance (in quiet and noise) and localization

Secondary outcome

2.

To determine the benefit of a CI in the functionally deaf ear of patients with

asymmetrical hearing loss with moderate to severe hearing loss in their best ear

in terms of quality of life and music perception

Study description

Background summary

Background
Cochlear implantation has become a standard treatment for patients with bilateral severe hearing to profound hearing loss. Rehabilitation with a CI is designed for the deafened subjects unable to have a good speech perception on both ears. A number of patients were seen recently who were in need for a better rehabilitation, but who had one ear in which their hearing aid was just sufficient to give them some speech performance. Their other ear functioned as a deaf ear. This unique group of patients are in between sufficient and insufficient hearing and because of their deaf ear they perform worse in noisy environments. Their understanding of speech in noise is worse than in patients with hearing aid use on both ears. These patients benefit from a CI in their deaf ear for speech intelligibility in noise, localization and probably benefit

in music perception, but this was never well documented. Overall we believe that their quality of life would improve subtantial. But up till now a study in this asymmetrical hearing loss group has not been performed because of this rare pathology and the focus on speech in quiet conditions instead of speech in noise, localisation and quality of life.
The aim of this study is to observe the benefits obtained by adults that have an asymmetrical cochlear hearing loss when wearing a CI in the worse ear and HA in the contralateral ear. Changes in perceptual abilities, speech production, localization abilities and music perception will be assessed over a 12 month period of use of the CI with HA.

Study objective

1.
To determine the benefit of a CI in the functionally deaf ear of patients with asymmetrical hearing loss with moderate to severe hearing loss in their best ear
in terms of speech performance (in quiet and noise) and localization

2.
To determine the benefit of a CI in the functionally deaf ear of patients with asymmetrical hearing loss with moderate to severe hearing loss in their best ear in terms of quality of life and music perception

Study design

Single center prospective non-randomised observational case-control study

Patients with an asymmetrical sensorineural hearing loss (SNHL) will be asked to enroll in the study prior cochlear implantation. Their hearing and questionnaires prior to implanation will be the baseline measurement. The results of the objective and subjective measures in the following year will be compared to these baseline results. A total of ten patients are planned to be included in the study

All subjects will be fitted by the audiology department in the VUmc according to the normal, clinical routine, similar to the care and follow-up of all cochlear implant patients in VUmc. All CI and Hearing aid settings will be optimized per subject. Testing shall be conducted pre implantation (baseline/*control*) and at 3, 6, and 12 months post implantation. Additional tests will be done objective testing (e.g. speech in noise) and questionnaires shall be applied at those time points. Twelve months after start of the CI rehabilitation is considered as endpoint.

Study burden and risks

All subjects will be fitted in the VUmc according to the normal, clinical routine. All CI settings will be optimized per subject. Testing shall be conducted pre implantation (baseline) and at 3, 6, and 12 months post implantation. A test battery comprising both objective testing and questionnaires shall be applied:

BURDEN
The number of TEST MOMENTS are EQUAL to the normal follow up moments. The number of tests has slightly increases, with an EXTRA TIME CONSUME of 4 times 2-3 hours.
The participants also need to fill in 2 EXTRA QUESTIONNAIRES at different time points

BENEFIT
The overall benefit for the patient and the group is to have a beter hearing. Even when not participating in this study we expect their hearing to improve with an CI.

RISKS
we expect no risks with the tests we use.

Speech tests: no risk
Localisation tests: no risk
Acoustical tests: no risk
Electrical tests:
Prevention is guaranteed for the two hazards that could possibly occur in this study: 1) overstimulation causing patient
discomfort, and 2) build-up of electrical charge on electrodes or tissue due to unbalanced stimulation.
ad 1) The overstimulation hazard is equal to this hazard in the normal CI fitting software and is controlled by restricting the
performance of these measurements to clinical physicists experienced in CI fitting.
2) The charge-unbalance hazard is prevented in the software provided by Advanced Bionics.
Both risks are equal to all cochlear implant user during rehabilitation.

TESTS
Pure Tone Audiometry
* (Un)Aided situation: thresholds (dBHL) will be measured on frequencies 125 - 8000Hz
Speech recognition
* NVA, Bosmanlijsten at 65 dB SPL (3 lists)
Speech recognition in noise
* DIN-test (digits in noise test), overall level fixed at 65 dBA
- Speech and noise frontal
Spatial speech recognition in noise

* DIN-test (digits in noise test), overall level fixed at 65 dBA
- Speech left, noise right (plus and minus 900)
- Speech right, noise left
Localization
* Localization of everyday sounds (8 loudspeakers)
Questionnaires
* NCIQ
* IOI-CI
Music perception
* Music evaluation questionnaire (Mirza et al, 2003)

Contacts

Public
Vrije Universiteit Medisch Centrum

de Boelenlaan 1117
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

de Boelenlaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Postlingually deafened adults aged 18 years and older
2. Bilateral cochlear hearing loss
o Worse ear speech scores: <30% speech perception *
o Better ear speech scores: 60-85% speech perception *
* speech scores are: best aided, phoneme (CVC), 65dB SPL

Exclusion criteria

1. Any reason why a cochlear implantation could not be performed (medical, audiological, linguistical, anestesiological, mental e.o.)
2. Participant in another clinical trail
3. Preference of another type of implant
4. Prelingual onset of hearing loss
5. <40% difference in speech perception between both ears
6. Binaural higher speech perception scores as compared to the better ear alone
7. Patient believes that there is a binaural advantage in speech perception as compared to the better ear alone

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):	21-10-2012
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	13-08-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-10-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL39637.029.12