SONATA : Study on the advantage of Two CI-Aids, a randomized controlled study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hearing disorders
Study type	Interventional

Summary

ID

NL-OMON39995

Source
ToetsingOnline

Brief title
SONATA

Condition

- Hearing disorders

Synonym
deafness, sensorineural hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Firma Med-El

Intervention

Keyword: adults, bilateral, cochlear implant

Outcome measures

Primary outcome

The main outcome will be the performance on the Amsterdam-Oldenburg Bilateral Benefit Battery for cochlear implants (AO-BBB-ci) test battery. This test battery evaluates the performance for speech perception in background noise with a spatial separation between the sound sources, horizontal localization, and listening effort.

Secondary outcome

Secondary outcome measures will be self-reported benefits in everyday listening situations assessed with the Speech, Spatial and Qualities Hearing Scale (SSQ), generic quality of life questionnaire scores (Health Utilities Index, HUI) and disease specific quality of life questionnaire scores (Nijmegen Cochlear Implant Questionnaire, NCIQ, and Tinnitus Handicap Inventory (THI).

Study description

Background summary

Normal-hearing listeners gain important benefits from having two ears. Users of a MED-EL cochlear implant (CI) achieve high levels of spoken word recognition when speech is presented in quiet. However, these users still experience difficulty in the presence of competing sounds and are poor at identifying where sounds come from. These limitations may be overcome, to some degree, by providing an implant to both ears. This study will investigate bilateral versus unilateral benefit in adults who are implanted with two MED-EL cochlear implants sequentially.

Study objective

The objectives are to evaluate the degree of bilateral benefit gained from having a second implant with respect to speech perception, spatial hearing, and

listening effort.

Study design

58 subjects with severe sensorineural hearing loss will be included in this Randomized Controlled Trial (RCT). 24 subjects shall receive one implant at the beginning of the study and a second implant after a period of two years at the end of this study (Group U). 24 subjects shall receive 2 cochlear implants sequentially, one upon inclusion and one 6 months after the first implantation (Group B). 10 subjects receiving a cochlear implant unilaterally that do not wish to participate in this study but do fulfil all other inclusion criteria and do not fulfil any of the exclusion criteria will be asked to complete all study questionnaires and will be used as a reference group (Group R).

Intervention

Bilateral cochlear implantation.

Study burden and risks

For both groups, the risks of a second surgical procedure are considered equal to the risks of the first surgery. When worsening of the health status of a subject no longer allows a second surgery, the subject will be excluded from further implantation. The evaluation consists of 6 or 7 test sessions of 2 hours each spread over a period of two years.

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

1. Age >= 18.
2. Postlingual onset of hearing loss, defined as an onset of hearing loss >= 6 years of age.
3. Sensorineural hearing loss of a severe or greater degree in both ears, defined as pure tone average (250, 500, 1000, 2000 Hz) >= 70 dB HL with no signs of a ski-slope audiogram.
4. Duration of severe-to-profound hearing loss <= 20 years in each ear and a comparable duration of severe-to profound hearing loss between both ears.
5. No signs of asymmetry > 30 dB in the past year.
6. Marginal hearing aid benefit with hearing aids, defined as speech perception <= 60% at 65 dB SPL upon optimal hearing aid fitting.
7. Dutch language proficiency.
8. Willingness and ability to participate in all scheduled procedures outlined in the protocol.
9. General health allowing general anaesthesia during two sequential surgical procedures to implant both cochlear implants.
10. Adequate coverage of one cochlear implant by a patient*s Dutch health insurance company.
11. Willingness to be implanted with cochlear implants from MED-EL.

Exclusion criteria

1. Previous implant experience.
2. Disability which could interfere with the completion of all tests.
3. Abnormal cochlear anatomy in one or both ears.
4. Chronic ear infection in one or both ears.
5. Psychosocial contraindication

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-08-2013
Enrollment:	58
Type:	Actual

Medical products/devices used

Generic name:	cochlear implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-01-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-03-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-01-2014
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	NL35640.018.11