Bilateral Cochlear Implantation Benefits in Adult Users of the HiRes 90K Bionic Ear System

Published: 10-11-2008
Last updated: 18-07-2024

1) Compare a group of bilateral users to a unilateral control group (between-subject design)2) Compare unilateral use to bilateral use after sequential implantation (within-subject design)3) Compare simultaneous bilateral implantation to sequential...

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

Summary

ID

NL-OMON33681

Source
ToetsingOnline

Brief title
Bilateral Cochlear Implantation (RCT)

Condition

- Hearing disorders
- Head and neck therapeutic procedures

Synonym
deaf, SNHL

Research involving
Human

Sponsors and support

Primary sponsor: Advanced Bionics Europe
Source(s) of monetary or material Support: Advanced Bionics => fabrikant van

cochleaire implantaten

Intervention

Keyword: Bilateral, cochlear implantation, RCT

Outcome measures

Primary outcome

Evaluate the benefits adults obtain from bilateral versus unilateral cochlear implant use.

Compare bilateral cochlear implant benefit after simultaneous versus sequential implantation

Primary parameter:

Performance on hearing in noise test with sentences in Dutch (Objective).

Secondary outcome

Evaluate the benefits adults obtain from bilateral versus unilateral cochlear implant use.

Compare bilateral cochlear implant benefit after simultaneous versus sequential implantation

Secundary parameters:

Objective:

Performance on Standard Dutch phoneme test (NvA-list, Bosman), Performance on Speech intelligibility with spatially separated sources, Performance on

Crescent of sound tests (Quentin Summerfield)

Subjective:

Self-reported benefits in everyday listening situations assessed with the

Speech, Spatial and Qualities Hearing Scale (SSQ),

Quality-of-life questionnaire scores, Tinnitus questionnaire scores.

Study description

Background summary

Based upon the advantages normal-hearing listeners gain from having two ears, upon the fact that users of two implants demonstrate quantifiable improved benefit over single-implant use, upon the need for studies in which the methodology strongly control for biases such as in Randomised Controlled Trials (RCTs), and upon preliminary data indicating that HiRes sound processing may provide enhanced binaural benefit, this study will use an RCT to investigate the benefits adults obtain from HiRes after simultaneous or sequential bilateral implantation.

Study objective

1) Compare a group of bilateral users to a unilateral control group (between-subject design)
2) Compare unilateral use to bilateral use after sequential implantation (within-subject design)
3) Compare simultaneous bilateral implantation to sequential bilateral implantation (between-subject design)

Study design

The study is a randomised controlled trial in which patients who fit within the inclusion criteria and who accept to take part in the study are randomly assigned to simultaneous or sequential bilateral implantation. Subjects assigned to simultaneous bilateral implantation shall receive two implants at the beginning of the study and shall be evaluated before surgery and after one and two years bilateral implant use. The group assigned to sequential implantation shall receive one implant at the beginning of the study, be evaluated before the first surgery and one and two years thereafter. After two

years of unilateral use, they will receive a second implant, with which they shall be evaluated after another one and two years of bilateral use. Performances and self-reported benefits will be measured for all subjects. The subjective outcomes will be compared to self-reported benefits (quality of life questionnaires) of 20 unrandomised subjects who will undergo regular unilateral cochlear implantation. The extra control group will only be recruited once the first 48 patients have been selected.

Intervention

Cochlear implant surgery

Study burden and risks

Compared to routine clinical practice, the study requires that the subjects undergo a second cochlear implantation either in an extended surgery (about an added 50 % surgical time) or in an additional second surgery after 2 years. This carries the usual risks associated with surgery and a slightly longer anaesthetic exposure. The clinical management will otherwise be unaffected besides appointment times being longer to ensure that both implants are optimally working.
Note: In the AMC we normally use a rapid surgical technique which in total reduces the total surgical time, compared to the classic procedure, with about 50%.

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 patients with bilateral sensorineural hearing loss of a severe or greater degree and with postlingual onset

Exclusion criteria

Previous cochlear implant experience, abnormal cochlear anatomy, non-fluent in Dutch, disabilities which could interfere with the tests.

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):	11-12-2009
Enrollment:	48

Type: Actual

Medical products/devices used

Generic name: Cochlear implants

Registration: Yes - CE intended use

Ethics review

Not available

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: 23027
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL24990.018.08