

Bilateral Cochlear Implantation in Adults (RCT).

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23027

Source

Nationaal Trial Register

Brief title

N/A

Health condition

severe sensorineural hearing loss
ernstig perceptief gehoorverlies

Sponsors and support

Primary sponsor: UMC Utrecht, ENT department

Source(s) of monetary or material Support: Advanced Bionics

Intervention

Outcome measures

Primary outcome

Performance on the STAR2 hearing test.

Secondary outcome

1. Performance on the Standard Dutch phoneme test, the Speech intelligibility test with spatially separated sources and the Crescent of sound test;
2. Self-reported benefits in everyday listening situations assessed with the SSQ;
3. Quality-of-life questionnaire scores;
4. Tinnitus questionnaire results.

Study description

Background summary

Brief summary:

This study will investigate bilateral versus unilateral benefit in adults who are implanted with two Bionic Ears either simultaneously or sequentially. The objective is to evaluate the degree of bilateral benefit gained from having a second implant. 48 Adult subjects with severe sensorineural hearing loss will be included in this Randomised Controlled Trial. Half of the group shall receive one implant at the beginning of the study and a second implant after a period of two years. The other half shall receive two cochlear implants simultaneously during one operation. Objective and subjective parameters will be measured during evaluation sessions pre-operatively, and 1 and 2 years after cochlear implantation.

Study objective

Normal-hearing listeners gain important benefits from having two ears. Users of a Bionic Ear achieve high levels of spoken word recognition when speech is presented in quiet. However they 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 Bionic Ears either simultaneously or sequentially.

Study design

1. Preoperatively;
2. 1 year post (first) implantation;
3. 2 years post (first) implantation;
4. In sequential implantation group: 1 and 2 years after second implantation.

Intervention

Simultaneous or sequential bilateral cochlear implantation.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 18-75;
2. Postlingual onset of hearing loss;
3. Severe Sensorineural hearing loss;
4. Duration of severe hearing loss <20 years;
5. Marginal hearing aid benefit with hearing aids;
6. Dutch language proficiency;
7. Willingness and ability to participate in all scheduled procedures outlined in the protocol;

8. General health allowing general anaesthesia for the potential implantation of two cochlear implants during a single surgery;
9. Patients covered by the Dutch health insurance;
10. Patients should agree to be implanted with cochlear implants from Advanced Bionics.

Exclusion criteria

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

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2009
Enrollment:	48
Type:	Actual

Ethics review

Positive opinion

Date: 11-03-2009
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 33681
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1625
NTR-old	NTR1722
CCMO	NL24990.018.08
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON33681

Study results

Summary results

N/A