

Bilateral Cochlear Implantation in Adults (RCT).

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23027

Bron

Nationaal Trial Register

Verkorte titel

N/A

Aandoening

severe sensorineural hearing loss
ernstig perceptief gehoorverlies

Ondersteuning

Primaire sponsor: UMC Utrecht, ENT department

Overige ondersteuning: Advanced Bionics

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Performance on the STAR2 hearing test.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

Simultaneous or sequential bilateral cochlear implantation.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2009
Aantal proefpersonen:	48
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	11-03-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 33681

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A