

Effects and costs of Bilateral Cochlear Implantation in Children (RCT).

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24087

Source

Nationaal Trial Register

Brief title

BICEPS

Health condition

Deafness

Hearing loss

Sponsors and support

Primary sponsor: University Medical Center Utrecht (UMCU), Department of ENT

Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Performance on the non-looking vocal turns (NLVT) component of the Tait video analysis in the individual patient;~s best aided condition.

Secondary outcome

1. Localisation abilities assessed with the:
 - A. Left-Right discrimination test;
 - B. Movement Tracking Test;
 - C. 3-alternative localisation test.
2. Assessment of speech perception in noise with the spatial release from masking (SRM) test;
3. Assessment of auditory pathway development with ABR and cortical auditory evoked potentials.

Study description

Background summary

This study will investigate the benefit of bilateral cochlear implantation over unilateral cochlear implantation in children who are implanted with two cochlear implants either simultaneously or sequentially. The objective is to evaluate the degree of bilateral benefit gained from having a second implant. 45 Children with severe to profound 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, 6, 12, 24, 36 and 48 months after the first cochlear implantation.

Study objective

Bilateral cochlear implantation in children has potentially an advantage over unilateral cochlear implantation in terms of communication development (both preverbal communication and language development) and sound localization. This study will compare the effects of simultaneous and sequential bilateral cochlear implantation. This not only allows to compare the effects of simultaneous and sequential bilateral cochlear implantation , but also of unilateral and bilateral cochlear implantation.

Study design

1. Preoperatively;
2. 6 months post (first) implantation;
3. 12 months post (first) implantation;

4. 24 months post (first) implantation;
5. 36 months post (first) implantation;
6. 48 months post (first) implantation.

Intervention

Simultaneous or sequential bilateral cochlear implantation.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age \geq 2 years;
2. Current clinically used cochlear implant criteria of the multidisciplinary cochlear implant team of the UMC Utrecht;
3. Willingness and ability of parents or guardians to participate in all scheduled procedures outlined in the protocol;
4. General health allowing general anaesthesia for the potential implantation of two cochlear implants during a single surgery;

5. Patients covered by the Dutch health insurance.

Exclusion criteria

1. Abnormal cochlear anatomy in one or both ears;
2. Chronic ear infection in one or both ears;
3. Previous implant experience;
4. Disability which could interfere with the completion of the tests;
5. Deafness caused by meningitis, otosclerosis or Cogans syndrome;
6. Severely visually impaired.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Suspended
Start date (anticipated):	02-04-2012
Enrollment:	45
Type:	Anticipated

Ethics review

Positive opinion

Date: 12-01-2012
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36764
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3084
NTR-old	NTR3232
CCMO	NL34845.041.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36764

Study results

Summary results

N/A