Bilateral cochlear implantation in children; a pragmatic randomised controlled trial

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To evaluate the effectiveness of bilateral implantation over unilateral implantation in children with severe-to-profound sensorineural hearing loss. Furthermore with this study we will investigate whether simultaneous bilateral implantation is...

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

Summary

ID

NL-OMON36764

Source
ToetsingOnline

Brief title
BiCI children

Condition

- Hearing disorders

Synonym
Deafness, Hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bilateral implantation, Children, Cochlear implantation

Outcome measures

Primary outcome

The primary outcome will be the performance on the TAIT video analysis.

Secondary outcome

Secondary outcomes will be the performance on:

- soundlocalization tests

- auditory perception measures

- electrophysiology tests: Auditory brainstem response (ABR) and Cortical

auditory evoked potentials (CAEP)

Study description

Background summary

Several studies show that bilateral cochlear implantation seems to have an added value compared to unilateral implantation in deaf children. However, these studies are of poor quality, which caused that The Dutch Health Care Insurance Board (College voor zorgverzekeringen) stated that there currently is insufficient evidence regarding the suggested beneficial effect of bilateral implantation over unilateral implantation and therefore they do not compensate the second cochlear implant for young children with severe-to-profound deafness. In order to provide conclusive evidence for bilateral cochlear implantation we aim to conduct a randomized controlled trial comparing simultaneous bilateral cochlear implantation with sequential bilateral implantation in children with severe-to-profound deafness.

Study objective

To evaluate the effectiveness of bilateral implantation over unilateral implantation in children with severe-to-profound sensorineural hearing loss. Furthermore with this study we will investigate whether simultaneous bilateral

implantation is preferable to sequential bilateral implantation.

Study design

45 subjects with severe-to-profound sensorineural hearing loss will be included in this Randomized Controlled Trial; 20 Subjects will be randomly allocated to receive two cochlear implants simultaneously during one operation (Group A), and the other 25 Subjects will be randomly allocated to receive one implant at the beginning of the study and a second implant after a period of two years (Group B). Both groups will be followed for 4 years after (the first) implantation.

Intervention

Group A: bilateral simultaneous cochlear implantation
Group B: bilateral sequential cochlear implantation

Study burden and risks

For group A subjects: the duration of surgery will be prolonged with approximately 50% of the standard operation time.
For group B subjects: the risks of the second surgery are considered equal to the risks of the first surgery.

All participants will be asked for seven additional visits to the outpatient clinic for additional evaluations. The duration of every visit will vary between 1 and 1.5 hours.
All parents of participants will be asked at every visit to complete two questionnaires. It takes approximately 15 minutes to complete the two questionnaires.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Cochlear implant candidacy, according to the current criteria
- Age < 2 years
- Written informed consent by parents or guardians
- General health allowing general anaesthesia for the potential implantation of two cochlear implants during a single surgery.
- Patients covered by the Dutch health insurance

Exclusion criteria

- General health not allowing general anaesthesia for the potential implantation of two cochlear implants during a single surgery.
- Abnormal cochlear anatomy in one or both ears.
- Chronic ear infection in one or both ears.
- Previous cochlear implant experience.
- Disability which could interfere with the completion of the tests.
- Deafness caused by meningitis, otosclerosis or Cogans syndrome.
- Severely visually impaired

Study design

Design

Study phase:	3
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):	14-05-2012
Enrollment:	45
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	04-04-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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: 24087
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL34845.041.10
OMON	NL-OMON24087