binaural hearing in children and teenagers with a severe hearing loss with bilateral hearing devices

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determine the effect of a HA in combination with a CI in children as well asdetermine the effect of bilateral cochlear implantation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ear and labyrinthine disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON31422

Source
ToetsingOnline

Brief title
Binaural hearing and severe hearing impairment

Condition

- Ear and labyrinthine disorders congenital

Synonym
congenital severe hearing loss

Research involving
Human

Sponsors and support

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

Intervention

Keyword: bilateral, bimodal hearing, children, cochlear implantation and hearing aid

Outcome measures

Primary outcome

results of individual patients on varied audiometric tests(directional

hearing,speech perception, evoked potentials)

Secondary outcome

not applicable

Study description

Background summary

Humans are hearing with two ears. This is the reason why they are hearing from which direction the sound comes from. Because of this it's possible to direct to the source of the sound and determine directly from which side possible danger is coming from.
Binaural hearing can also reduce the negative influence of disturbing sounds on speech perception.
Patients with severe hearing loss and a unilateral cochlear implant (CI) or with a unilateral hearing aid (HA) cannot hear binaurally.
In the case of contralateral useful residual hearing in children with CI it is often advised to use a hearing aid contralateral.This is called bimodal adaptation.
Also, a few deaf children are provided with a bilateral cochlear implant (bilateral adaptation).
There is little evidence of binaural advantage in adult CI-patients with contralateral a HA.This advantage is still not demonstrated enough, especially not for children with a congenital severe hearing loss (Ching e.a., 2005).
Moreover,the effect of the variables:gravity of the hearing loss and duration of absence of stimulation on the non-implanted ear or the ear that is implanted secondly, is not known.
It is also not known if it is possible to obtain binaural hearing in all deaf children after bilateral cochlear implantation.Publications with regard to postlingual deaf adult CI-users show that an advantage of bilateral implantation can be expected, for example in directional hearing (Muller 2002, Stark 2002, Au 2003, Das 2005).Publications of studies of binaural hearing in

bilateral implanted children, are still rare.

Study objective

determine the effect of a HA in combination with a CI in children as well as determine the effect of bilateral cochlear implantation.

Study design

Observational study without invasive measurements

Study burden and risks

parents fill in a few questionnaires about health of the child and its audiologic functioning in different situations of every day life
There are no risks for the child participating in this study and the burden for the subject is very small.
For parents it is very useful to know what the advantage is of the CI or the HA. With the results parents can be advised towards the use of the CI or HA.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

children and teenagers, age 5 to 20 with a normal intelligence.
These children have a severe hearing loss and have at least unilateral a cochlear implant and contralateral a cochlear implant or a hearing aid

Exclusion criteria

additional handicaps as mental retardation

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2007
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL16772.091.07