Effect of simultaneous bilateral cochlear implantation in prelingually deaf children

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To assess the effect of bilateral cochlear implantation compared to the standard unilateral cochlear implantation in children with severe to profound hearing loss.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hearing disorders
Study type	Observational non invasive

Summary

ID

NL-OMON34464

Source
ToetsingOnline

Brief title
Simultaneous bilateral cochlear implantation

Condition

- Hearing disorders

Synonym
prelingual deafness

Research involving
Human

Sponsors and support

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

Intervention

Keyword: children, cochlear implants, deafness, development

Outcome measures

Primary outcome

The difference in results between the study group and the control group on

auditory, language and psychological tests.

Secondary outcome

not applicable

Study description

Background summary

Humans can hear with two ears, after which a central integration of the perceived sound occurs. This is often called binaural hearing. Therefore, one is able to locate sound. This enables the listener to focus on the sound source and to determine quickly on which side possible danger originates from. Binaural hearing can also reduce the negative influence of disturbing sounds on speech perception, which consequently improves the speech perception.

Patients with severe to profound deafness, who are provide with a unilateral cochlear implant (CI), are unable to hear binaurally. Literature shows improved speech perception as well as localisation in children with bilateral CIs compared to listening with a unilateral CI [Sparreboom M et al. The effectiveness of bilateral cochlear implants for severe to profound deafness in children: a systematic review. Accepted for publication 2010]. However, in the Netherlands, the provision of bilateral CIs is not standard health care. As the majority of prelingual deaf children with a CI without additional handicaps attend to mainstream school settings, the consequence of unilateral fitting is a serious matter of concern. Research showed that school-age children with several degrees of unilateral hearing loss were at risk for speech-language delays and educational grade failures [Lieu, 2004]. As a result of improved speech perception in noise, it is expected that the advantage of bilateral CIs can be particularly found in the possibility to learn incidentally. In prelingually deaf children with a unilateral CI this is generally more difficult.

In 2009 the Dutch Health Care Insurance Board indicated that at this moment the available evidence is not sufficient enough to approve the advantage of bilateral cochlear implantation in children compared to children with a unilateral CI. They indicate that reconsideration will occur if publications

from Dutch origin become available on speech perception and the acquisition of spoken language in children with prelingual severe to profound hearing loss with bilateral CIs.

Study objective

To assess the effect of bilateral cochlear implantation compared to the standard unilateral cochlear implantation in children with severe to profound hearing loss.

Study design

Observational study

Study burden and risks

Subjects will be investigated once, in which they will not be at any risk and the burden for the subject will be very small. Parents will fill in questionnaires with regard to the psychosocial functioning of their child. As the study aims on development, which occurs during the first years of life, the study will be administered in minors. As the Dutch Health Care Insurance Board have approved the initiative for the intended study, we feel that, in the light of the very small burden for the children, the study is justified.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Children, age 3.5 to 8 years old
- Severe to profound prelingual hearing loss
- Implanted simultaneously with bilateral CIs or with a unilateral CI, before the age of 3 years
- At least 2 years of CI experience
- Native language: Dutch

Exclusion criteria

- Cognitive, learning and/or behavioural deficits
- Partial insertion of the CI
- Benefit from a contralateral conventional hearing aid

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2011
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	04-11-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-11-2011
Application type:	Amendment
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	NL33019.091.10