# 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 reviewApproved WMOStatusRecruitment stoppedHealth condition typeHearing disordersStudy typeInterventional

# **Summary**

#### ID

NL-OMON36764

#### Source

ToetsingOnline

**Brief title**BiCl 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

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#### Scientific

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## **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