To investigate the cost-effectiveness of day-case cochlear implantation compared to inpatient cochlear implantation and the effect of both methods on quality of life.

**Ethical review**  Approved WMO

**Status**  Completed

**Health condition type**  Hearing disorders

**Study type**  Interventional

### Summary

**Source**

ToetsingOnline

**Brief title**

DAY-CI

**Condition**

- Hearing disorders

**Synonym**

deafness, severe to profound bilateral sensorineural 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 :  Cochlear implantation, Day-case, Inpatient, RCT
Outcome measures

Primary outcome

Primary outcome measure is general quality of life measured by the Health Utility Index - Mark 3.

Secondary outcome

Secondary outcome measures are disease-specific quality of life, complications and cost-effectiveness.

Study description

Background summary

Cochlear implantation is an increasingly common procedure in the treatment of severe to profound sensorineural hearing loss in children and adults. In other Western countries, cochlear implantation is increasingly performed as a day-case procedure. The major drive toward day-case surgery has been financial, but most likely positively influences the patient’s quality of life as a result of rapid discharge and rehabilitation. Even though cochlear implantation seems well suited to a day-case approach, given the low complication rates and early recovery, evidence is scarce and of low quality.

Study objective

To investigate the cost-effectiveness of day-case cochlear implantation compared to inpatient cochlear implantation and the effect of both methods on quality of life.
Study design

Un-blinded randomized controlled trial.

Intervention

Day-case versus inpatient surgery.

Study burden and risks

Compared to routine clinical practice, the study requires that half of the participants undergo day-case surgery instead of inpatient surgery. A risk of unforeseen (overnight) admittance following day-case surgery is present. The benefits of day-case surgery are early discharge and early social and emotional rehabilitation.

Contacts

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Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)
Inclusion criteria

Age >= 18 years;
Severe to profound bilateral post-lingual sensorineural hearing loss defined as >= 70 dB nHL on pure-tone audiometry in the range of 500, 1000 and 2000 Hz;
Willingness and ability to participate in all scheduled procedures outlined in the research protocol;
General health allowing general anesthesia in an outpatient setting;
Quick access to communication and transportation in case of any complications;
Good understanding of the Dutch language.

Exclusion criteria

Severe to profound pre-lingual sensorineural hearing loss;
Severe to profound unilateral sensorineural hearing loss;
Previous cochlear implantation;
Aberrant (cochlear) anatomy on CT-scan or chronic ear infection;
General health does not allow general anesthesia in an outpatient setting;
Disability that could interfere with audiologic evaluation and/or questionnaire fulfillment.

Study design

Design

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

Recruitment

NL
Recruitment status : Completed
Start date (anticipated) : 17-04-2014
Enrollment : 30
Type : Actual
Ethics review

Approved WMO Date: 11-12-2013
Application type: First submission
Review commission: METC NedMec

Approved WMO Date: 31-03-2015
Application type: Amendment
Review commission: METC NedMec

Approved WMO Date: 22-12-2015
Application type: Amendment
Review commission: METC NedMec

Approved WMO Date: 28-03-2018
Application type: Amendment
Review commission: METC NedMec

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

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