Day-case cochlear implantation compared to in-patient cochlear implantation in patients with severe to profound hearing loss.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26971

Source
NTR

Brief title
DAY-CI

Health condition

Severe to profound sensorineural hearing loss.

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: University Medical Center Utrecht

Intervention

Outcome measures

Primary outcome

General quality of life measured by the Health Utilities Index - Mark III at three weeks

postoperatively.

Secondary outcome

• Complications;
• Disease specific quality of life using the Glasgow Health Status Questionnaire and the Glasgow Benefit Inventory;
• General quality of life using the EuroQol-5D;
• Tinnitus using the Tinnitus Handicap Inventory, Tinnitus Questionnaire and Utrecht Tinnitus Burden Questionnaire for severity of tinnitus;
• Vertigo using the Utrecht Vertigo Burden Questionnaire;
• Cost-utility analysis using a costs diary.

Study description

Background summary

SUMMARY

Rationale: cochlear implantation is an increasingly common procedure in the treatment of severe to profound sensorineural hearing loss in children and adults. Through electrical stimulation of the auditory nerve, an improvement in perception of sound and speech is achieved. 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.

Objective: to investigate the cost-effectiveness of day-case cochlear implantation compared to inpatient cochlear implantation and the effect of both methods on hearing outcomes, quality of life and complication rates.

Study design: un-blinded randomized controlled trial.

Study population: adult patients with severe to profound post-lingual sensorineural hearing loss, aged 18 years and over, who are eligible for cochlear implantation.

Intervention: day-case or inpatient surgery.

Main study parameters/endpoints: primary outcome measure is general quality of life measured by the Health Utility Index – Mark III. Secondary outcome measures are hearing improvement, disease-specific quality of life, complications and cost-effectiveness.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: compared to routine clinical practice, the study requires half of the participants

to undergo day-case surgery instead of inpatient surgery. A risk of unforeseen (overnight) admittance following day-case surgery is present. The possible benefits of day-case surgery are early discharge and early social and emotional rehabilitation.

Study objective

Day-case cochlear implantation is associated with higher quality of life and higher cost-effectiveness, while maintaining equal hearing results and adverse events, compared to in-patient cochlear implantation.

Study design

Follow-up directly postoperatively, at three weeks postoperatively and at one year postoperatively. Furthermore a monthly costs diary will be fulfilled.

Intervention

A day-case versus an inpatient approach for cochlear implantation. Day-case surgery involves same-day admittance and discharge, whereas inpatient surgery involves admission the day before surgery and discharge two days after surgery. Hearing outcomes, quality of life, complication rates and cost-effectiveness will be evaluated using audiological tests and questionnaires following both methods.

Contacts

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Eligibility criteria

Inclusion criteria

• Age ≥ 18;
• Severe to profound 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 out-patient 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;
• Previous cochlear implantation;
• Aberrant (cochlear) anatomy on CT-scan or chronic ear infection;
• Disability that could interfere with questionnaire fulfillment.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2014
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-03-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44709
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4311
NTR-old	NTR4464
CCMO	NL45590.041.13
OMON	NL-OMON44709

Study results