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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26971

Bron
Nationaal Trial Register

Verkorte titel
DAY-CI

Aandoening

Severe to profound sensorineural hearing loss.

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: University Medical Center Utrecht

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2014
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-03-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44709
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten