CINGLE-studie: Cochleaire Implantatie bij siNGLE-sided deafness

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Patients who develop single-sided deafness (SSD) become aware of the importance of hearing with two ears in everyday listening environments. Current clinical practice for patients with SSD consists of optimizing hearing using a Bone Conduction…

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

Samenvatting

ID

NL-OMON26952

Bron
Nationaal Trial Register

Verkorte titel
CINGLE

Aandoening

single-sided deafness, unilateral hearing loss, single-sided hearing loss, unilateral deafness, eenzijdige doofheid, unilaterale doofheid, eenzijdig gehoorverlies, unilateraal gehoorverlies

Ondersteuning

Primaire sponsor: Department of Otorhinolaryngology and Head & Neck Surgery University Medical Center Utrecht, Utrecht, The Netherlands
Overige ondersteuning: Cochlear

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Performance on the modified Plomp hearing test.

Toelichting onderzoek

Achtergrond van het onderzoek

CINGLE-trial: Cochlear Implantation for siNGLE-sided deafness

Rationale: Patients who develop single-sided deafness (SSD) become aware of the importance of hearing with two ears in everyday listening environments. Current clinical practice for patients with SSD consists of optimizing hearing using a Bone Conduction Device (BCD) or a Contralateral Routing of Sound system (CROS). With both devices sound awareness on the deaf side can be improved, but they do not provide bilateral auditory input, which is needed to achieve the actual benefits of hearing with two ears. These limitations may be overcome by providing a cochlear implant (CI) and consequently generating auditory input to the affected ear.

Objective: The objectives of this study are to evaluate the clinical outcomes gained from having a cochlear implant (CI) over standard health care therapy with either BCD or CROS in patients with SSD and to examine the cost utility of cochlear implantation in these patients.

Study design: 120 subjects with acute (≥3 months and ≤10 years onset) SSD will be included in this Randomised Controlled Trial (RCT) after their informed consent. 30 Subjects shall receive a CI on the deaf side after randomisation (Group A). The other 90 subjects shall start with a 6-week during test period with either a BCD on a headband (n = 45, Group B) or with a CROS (n = 45, Group C). After these 6 weeks, patients in group B switch to a test period with a CROS for 6 weeks and vice versa for patients in group C. After completing both test periods patients in group B and group C will choose for further treatment with a CROS, a definitive surgically implanted BCD or no treatment. The follow-up sessions will take place 3, 6, 12, 18, 24, 36, 48 and 60 months after randomisation for participants in all groups.

Study population: 120 subjects aged 18 or older with postlingual SSD who are eligible for cochlear implantation.

Intervention (if applicable): Cochlear Implantation versus BCD or CROS

Main study parameters/endpoints: The main outcome will be the performance on the modified Plomp hearing test. Secondary outcome measures will be: performance on the Standard Dutch phoneme test (NvA-list), the Speech intelligibility test with spatially separated sources, the Crescent of sound test (Quentin Summerfield), self-reported benefits in everyday listening situations and quality of life assessed with the Speech, Spatial and Qualities Hearing Scale (SSQ), Abbreviated Profile of Hearing Aid Benefit (APHAB), Health Utilities Index (HUI3), Glasgow Benefit Inventory (GBI), Hospital Anxiety and Depression Score (HADS), Time Trade-Off (TTO), Visual Analogue Scales (VAS) and EuroQol-5D (EQ5D) and tinnitus questionnaires (Tinnitus Handicap Inventory [THI], Tinnitus Questionnaire [TQ] and Tinnitus Burden Questionnaire). Participants will keep a monthly diary to assess cost utility.

Doel van het onderzoek

Patients who develop single-sided deafness (SSD) become aware of the importance of hearing with two ears in everyday listening environments. Current clinical practice for patients with SSD consists of optimizing hearing using a Bone Conduction Device (BCD) or a Contralateral Routing of Sound system (CROS). With both devices sound awareness on the deaf side can be improved, but they do not provide bilateral auditory input, which is needed to achieve the actual benefits of hearing with two ears. These limitations may be overcome by providing a cochlear implant (CI) and consequently generating auditory input to the affected ear.

Onderzoeksopzet

Baseline and 3, 6, 12, 18, 24, 36, 48 and 60 months post-activation

Onderzoeksproduct en/of interventie

Randomised:

Cochlear Implantation (CI) versus Bone Conduction Device (BCD) or Contralateral Routing of Sound system (CROS)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age 18 or older.

- Acute onset of postlingual SSD, defined as onset unilateral hearing loss between ≥3 months and ≤10 years before time of inclusion.

- Hearing measurements:

> Pure Tone Audiometry of the deaf ear, defined as thresholds of 70 dB or higher on frequencies 0,5 – 4.0 kHz (average).

> Normal hearing on the contralateral ear, defined as pure tone audiometry thresholds of 30 dB or less on frequencies 0.5 – 4.0 kHz (average).

> Air bone gap 10 dB or smaller.

- Normal function of middle ear (i.e. no acute middle ear infections or tympanic membrane perforations).

- Dutch language proficiency.

- Willingness and ability to participate in all scheduled procedures outlined in the protocol.

- General health allowing general anaesthesia for the potential surgical implantation of a CI or BCD.

- Patients covered by the Dutch health insurance.

- Patients should agree to be implanted with a CI or BCD.

- Informed consent understood, filled out and signed by patient.

- Patients are not allowed to participate in another ongoing research study related to SSD or cochlear implantation

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- previous experience with implanted BCD or CI

- retrocochlear pathology - abnormal cochlear anatomy in one or both ears (i.e. ossification)

- disability which could interfere with the completion of the tests (i.e. psychiatric problems or severe comorbidity with an expected survival of less than five years)

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-07-2014
Aantal proefpersonen:	120
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	06-05-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4457
NTR-old	NTR4580
CCMO	NL45822.041.13

Resultaten

Samenvatting resultaten
Study protocol:
https://bmcearnosethroatdisord.biomedcentral.com/articles/10.1186/s12901-015-0016-y