Cochlear Implantaton for siNGLE-sided seafness

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Interventional

Summary

ID

NL-OMON44754

Source
ToetsingOnline

Brief title
CINGLE-trial

Condition

- Inner ear and VIIIth cranial nerve disorders

Synonym
single sided deafness, unilateral sensorineural hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Cochlear NV

Intervention

Keyword: BAHA, cochlear implantation, CROS, single sided deafness

Outcome measures

Primary outcome

Performance on USTARR speech in noise test (see C1)

Secondary outcome

- Performance on the Standard Dutch phoneme test (NvA-list)

- Speech intelligibility test with spatially separated sources

- Crescent of sound test, for sound localization

- Speech, Spatial and Qualities of hearing scale (SSQ); questionaire to objectify several domains of hearing

- Health Utilities Index (HUI3): questionnaire for general quality of life

- Glasgow Benefit Inventory (GBI); questionnaire for general quality of life after surgery

- Abbreviated Profile of Hearing Aid Benefit (APHAB); questionnaire for quality of hearing on several subdomains

- Time Trade Off (TTO); quality of life question

- Visual Analogue Scale (VAS); questionnaire on quality of life and hearing

- EuroQol5D; questionnaire on quality of life

- Hospital Anxiety and Disorder Scale (HADS); questionnaire objectifying anxiety and depression

- Tinnitus Handicap Inventory (THI): tinnitus questionnaire

- Tinnitus Questionnaire (TQ): tinnitus questionnaire

- Tinnitus Burden Questionnaire (TBQ); tinnitus questionnaire

- Cost diary for cost utility analysis

- CI-patients: vocoder and pitch match experiments

Study description

Background summary

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 Anchored Hearing Aid (BAHA) or a Contralateral Routing of Sound System (CROSS). With both devices sound awareness on the deafened 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. This study will investigate the benefit of cochlear implantation versus treatment with BAHA or CROSS in patients with SSD. CI patients will be able to compare sounds in their CI ear to sounds in their normal hearing ear, enabling us to perform pitch match and vocoder experiments (see C1).

Study objective

The objectives of this study are to evaluate the clinical outcome of a cochlear implant (CI) over standard health care therapy with either BAHA or CROSS in patients with SSD and to examine the cost efficiency of cochlear implantation in these patients. In CI patients pitch match and vocoder experiments will be performed.

Study design

120 subjects with acute (>=3 months and <=10 years since onset) SSD will be included in this Randomised Controlled Trial (RCT). 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 BAHA on a headband (n = 45, Group B) or with a CROSS (n = 45, Group C). After these 6 weeks, patients in group B switch to a test period with a CROSS 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 CROSS, a definitive surgically implanted BAHA 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.

Intervention

Cochlear Implantation versus BAHA or CROSS

Study burden and risks

The study is considered a non-significant risk evaluation of routine modalities for SSD in clinical practice (BAHA and CROSS) compared to a modality, cochlear implantation, which is already commonly clinically applied in patients with bilateral hearing loss. The evaluation consists of 7 test sessions of 2 hours each, spread out over five years of time, excluding the cost diary.

adverse events:
- standard risks associated with cochlear implantation or BAHA-placement
- standard risks associated with general anaesthesia
- associated with CI and BAHA: implant failure, irritation, pain, infection, implant extrusion
- associated with CI (following electrical stimulation): tinnitus, facial nerve stimulation, dizziness, uncomfortably loud sound sensation or no sound sensation due to failure of implant (components).

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- 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 BAHA.
- Patients covered by the Dutch health insurance.
- Patients should agree to be implanted with a CI or BAHA.
- 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

Exclusion criteria

- previous experience with implanted BAHA 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)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-07-2014
Enrollment:	120
Type:	Actual

Medical products/devices used

Generic name:	cochlear implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	06-05-2014
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	21-09-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	28-12-2017
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

Register	ID
CCMO	NL45288.041.13
Other	trialregister.nl, NTR4580