Assessment of degeneration of the auditory nerve by diffusion tensor imaging in unilaterally and bilaterally deaf adults

Published: 21-12-2015
Last updated: 19-04-2024

Firstly, comparison of DTI outcome variables between the auditory nerve of a deaf ear with that of a normal ear. Secondly, in patients who receive a CI, DTI measures will be compared to measures derived from electrically evoked compound action...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ear and labyrinthine disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON45145

Source
ToetsingOnline

Brief title
Diffusion tensor imaging of the auditory nerve

Condition

- Ear and labyrinthine disorders congenital
- Hearing disorders

Synonym
deafness, 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 nerve, deaf, degeneration, imaging

Outcome measures

Primary outcome

Comparison of fractional anisotropy (FA) and mean diffusivity (MD) of the auditory nerve between normal and deaf sides Furthermore, FA and MD will be correlated with duration of deafness. Other DTI metrics may be considered as well.

Secondary outcome

Correlation between the DTI parameters and eCAP parameters of patients who receive a CI. Correlation of DTI and eCAP parameters with duration of deafness. Reproducibility of DTI measures.

Study description

Background summary

A cochlear implant (CI) can restore hearing in patients with profound sensorineural hearing loss by direct electrical stimulation of the auditory nerve. A good condition of the auditory nerve is of paramount importance to bring about satisfactory hearing results after cochlear implantation. However, degeneration of the auditory nerve occurs as a result of cochlear hair cell loss and the extent of degeneration may vary between the two ears in bilaterally deaf (BD) patients. In most cases, one ear is implanted. It is therefore important to choose the ear with the best nerve, which presumably will give the greatest benefit of a CI. In a recent pilot study in 10 subjects (METC 13-493) we have demonstrated that diffusion tensor imaging (DTI), a magnetic resonance imaging (MRI) technique, can be used to visualize the

auditory nerve (Vos et al. 2015). A quantified DTI measure showed differences between unilaterally deaf (UD) patients and control subjects, but no differences between the normal and deaf side within the UD patients.

Study objective

Firstly, comparison of DTI outcome variables between the auditory nerve of a deaf ear with that of a normal ear. Secondly, in patients who receive a CI, DTI measures will be compared to measures derived from electrically evoked compound action potentials (eCAPs).

Study design

This is an observational study performed at the University Medical Center Utrecht (UMCU). Patients with UD who will receive a CI and patients with BD who will receive a CI, and healthy volunteers will undergo DTI. The UD and BD patients will be subject to eCAP recordings directly after implantation.

Study burden and risks

The used techniques in this study are audiometry, MRI, and eCAP recording. Normal-hearing subjects undergo 15 minutes audiometry. All patients and 10 of the normal-hearing control subjects undergo an MRI scan of approximately 30 minutes. The remaining 10 control subjects will participate in 4 MRI sessions of 30 minutes. In all patients a session of 15 minutes eCAP recordings will be performed in addition to clinical eCAP recordings performed under anesthesia immediately following CI surgery. The risks of these techniques are negligible, and not different from when used a routine clinical setting. No immediate benefits for individual subjects are to be expected from participation in this study. However, the knowledge derived from this study could facilitate the choice for the best ear to implant in patients with BD.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Aged 18 or older
- Normal function of middle ear, i.e., no acute middle ear infections, no tympanic membrane perforations and an air bone gap (which reflects middle-ear function) < 10 dB.;Additional inclusion criteria for unilateral deaf groups (same as in CINGLE trial):
- Hearing in *deaf* ear: hearing threshold for individual frequencies (0.5, 1, 2, 4 kHz) >= 70 dB HL.
- *Deaf* ear has been deaf for no longer than 10 years
- Hearing in *normal* ear: hearing threshold for individual frequencies (0.5, 1, 2, 4 kHz) <= 30 dB HL. Note that near-normal hearing is included by applying a less stringent criterion than for the normal-hearing subjects.;Additional inclusion criteria for bilateral deaf group:
- Admitted by cochlear implant team of the UMCU for cochlear implantation based on various clinical criteria.
-Implanted with a CI from manufacturer MED-EL or Cochlear;Additional inclusion criteria for normal-hearing group:
- Hearing within normal range: hearing threshold for individual frequencies <= 25 dB HL
- Average hearing threshold over 0.5,1,2 and 4 kHz <= 15 dB HL.

Exclusion criteria

A subject who meets any of the following criteria will be excluded from participation in this study:
- Abnormal cochlear anatomy in one or both ears (i.e. malformation or ossification).

- Disability which could interfere with the completion of the tests (i.e. psychiatric problems).
- Patients with contraindications for Magnetic Resonance Imaging (MRI) - not fulfilling the criteria of the MRI inclusion list, including the presence of a pacemaker and pregnancy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-09-2016
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	CIPT-system (Cochlear Implant Psychophysics Test system)
Registration:	No

Ethics review

Approved WMO Date:	21-12-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-01-2018

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL53077.041.15