An explorative study on cortical activation in normal hearing and in deaf adults, before and after cochlear implantation, measured with fMRI and NIRS.

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

Summary

ID

NL-OMON32742

Source
ToetsingOnline

Brief title
Measurement of cortical hemodynamics using fMRI or NIRS

Condition

- Ear and labyrinthine disorders congenital
- Hearing disorders

Synonym
sensorineural hearing loss, severe hearing loss and deafness

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Het onderzoek wordt gefinancierd uit een speciaal budget dat bestemd is voor onderzoek naar cochleaire implantatie. Dit budget is samengesteld uit de derde en vierde geldstroom. Nummer van dit budget is RN00083.

Intervention

Keyword: auditory cortex, cochlear implantation, fMRI, NIRS

Outcome measures

Primary outcome

A fMRI scan measured the cerebral blood flow (and hence the cortical activity)

by differences in the regional Blood Oxygen Level Dependent (BOLD) response

between activated and baseline (or control) condition.

To study the brain activity with NIRS, local changes in cortical oxy- and

deoxyhemoglobin concentration are evaluated.

Secondary outcome

not applicable

Study description

Background summary

A cochlear implant (CI) is a implantable electronic device that provides hearing sensations to patients with profound or total sensorineural hearing loss. Most of the children and postlingually deafened adults have favourable outcomes after implantation, however the benefits provided by CI*s display a great variability in adults who lost their hearing ability before the development of speech and language, the so-called *pre-lingually deaf* candidates. The prediction of substantial communication benefits after cochlear implantation is still a clinical dilemma. Until now, no objective tests have been described to predict the outcome of implantation in this pre-lingual

patient group. Previous studies suggest that probably PET could be used to assess glucose-metabolism in the auditory cortex pre-operatively in order to predict postimplantation CI results. However, this imaging technique has the disadvantage that patients had to be injected with an isotope.

To examine brain activation in the auditory cortex, without using an isotope, functional Magnetic Resonance Imaging (fMRI) can be an effective tool. Probably an fMRI scan can be used as an effective non-invasive tool to predict the postoperative hearing performance with CI. After implatation, probably NIRS can be used to investigate the hemodynamic response.

A relation is expected between hearing performance in implanted (pre-lingually) deaf patients on the one hand and cortical hemodynamic response on the other.

Study objective

The primary objective of the present study is to increase our insight in the neural processing in pre-lingually deaf and implanted patients, regarding the prediction and explanation of postoperative differences in performance within this specific group of cochlear implant users. To that end we will investigate:
a. the predictive value of brain hemodynamic response, measured by fMRI, on postoperative behavioural responses in pre-lingually deaf patients with residual hearing (study A)
b.If NIRS can be used as objective tool for evaluating the cortical activity in implanted patients (study B)

Study design

Two explorative studies:

Study A
In order to investigate the predictive value of brain hemodynamic response 10 pre-lingually deaf candidates for cochlear implantation will be evaluated one month before surgery. Also a normal hearing group will be measured, in order to relate cortical hemodynamic responses of prelingually deaf patients with normal hearing subjects.

In one scan-session 3 conditions will be measured: without stimulation, with auditory stimulation and with visual stimulation.

Study B
In order to investigate the differences in hemodynamic response between between good and poor performers with CI and to relate these results to normal hearing subjects, three groups will be investigated: 10 pre-lingually deaf implanted patients with a good result, 10 pre-lingually deaf implanted patients with a poor result, 10 normal hearing healthy volunteers. Each subject

participates 1 NIRS measurement. During the measurement 3 conditions will be investigated: without stimulation, with auditory stimulation and with visual stimulation.

Study burden and risks

For both measurements no risks are expected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Adults (18 years of age or older)
2. Right handed

3. Normal hearing group: having a pure-tone air conduction thresholds <= 15 dB HL
4. Unilaterally implanted pre-lingual deaf group: profound sensorineural hearing loss during the first 1.5 years of life
a. Implanted group with good results: consonant-vowel-consonant (CVC) score > 50% (open-set monosyllable lists according to the *Nederlandse Vereniging van Audiologie* (NVA)).
b. Implanted group with poor results: consonant-vowel-consonant (CVC) score < 50% (open-set, monosyllable lists according to NVA).
5. Prelingual deaf CI candidates: deaf or profound sensorineural hearing loss during the first 3 years of life, 90 dB < Pure tone average <120 dB

Exclusion criteria

1.Pregnancy/breastfeeding
2.Subjects with intracorporeal metal components or electronic devices
3.Claustrophobic

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	18-08-2008
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL24364.091.08