Cortical activation in pre-lingually deaf adults, with and without a cochlear implant

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

Summary

ID

NL-OMON31996

Source
ToetsingOnline

Brief title
Cortical activation in pre-lingually deaf adults

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, auditory evoked potentials, cochlear implantation, positron emission tomography

Outcome measures

Primary outcome

The cerebral glucose metabolism (and hence the cortical activity) is measured

by the regional [18F]-FDG uptake ([18F]-FDG is an analogue for glucose).

To study the auditory neural processing with ERPs, the amplitude, latency and

morphology of the N1, P2 and P300 responses are evaluated.

Secondary outcome

not aplicable

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.

In order to asses the hearing performance after cochlear implantation in an

objective way, *Event Related Potentials* (ERPs) can be used to study auditory neural processing on a cortical level using conventional EEG techniques.

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

Study objective

The primary objective of the present study is to increase our insight in the neural processing of speech in pre-lingually deaf CI 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 differences in performance of pre-lingually deaf patients with a cochlear implant (study A).
b. the differences in cortical activity between normal hearing and implanted pre-lingually deaf patients (study A).
c. the predictive value of brain metabolism, measured by PET scanning, on postoperative behavioural and objective electrophysiological responses in pre-lingually deaf patients (study B).
d. the cross-modal plasticity before and short and long term after implantation (study B).

Study design

Two observational studies:

Study A
In order to investigate the differences between between good and poor performers with CI and to relate these results to normal hearing subjects, three groups will be investigated: five pre-lingually deaf implanted patients with a good result, five pre-lingually deaf implanted patients with a poor result, five normal hearing healthy volunteers. Each subject participates in 3 PET studies (1 scan without stimulation, 1 scan with auditory stimulation and 1 scan with visual stimulation) and 1 ERP measurement.

Study B
In order to investigate the predictive value of brain metabolism and to investigate the cross-modal plasticity before and short and long term after implantation 13 pre-lingually deaf candidates for cochlear implantation will be evaluated one month before surgery, half a year after implantation and two years after implantation.
One months before surgery they will participate in 2 PET-studies (1 scan without stimulation, and 1 scan with visual stimulation). Half a year and 2 years after surgery they will participate in 3 PET studies (1 scan without

stimulation, 1 scan with auditory stimulation and 1 scan with visual stimulation) and 1 ERP measurement.

Study burden and risks

Study A:

Subject will participate in three 120 MBq [18F]-FDG PET-CT studies. The radiation load in this study is 7.4 mSv in two weeks (3 times an intravenous injection of 120 MBq [18F]-FDG PET corresponds with 6.8 mSv plus 3 times CT-scan corresponds with 0.6 mSV). All scans will be performed on 3 different days within two weeks. Before one of the three scans the subjects participate in the ERP experiment. No adverse events or risks are suspected.

Study B:

The radiation load in this study is 19.8 mSv in 2 years (8 times an intravenous injection of 120 MBq [18F]-FDG corresponds with 18.2 mSv in 2 years plus 8 times CT-scan corresponds with 1.6 mSV).
The preoperative scans are performed 1 month before surgery, on 2 different days, within one week.
The postoperative scans are performed on 3 different days, spread over 2 weeks. Before one of the three postoperative scans the subjects participate in the ERP experiment. These postoperative investigations are performed half a year and two years after implantation. No adverse events or risks are suspected.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Philips van Leydenlaan 15
6500 HB Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Philips van Leydenlaan 15
6500 HB Nijmegen
NL

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: total or 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: profound sensorineural hearing loss during the first 1.5 years of life, Pure tone average > 90 dB and < 10% open-set speech recognition (monosyllable lists, according to NVA).

Exclusion criteria

1.Pregnancy/breastfeeding
2.Diabetis Mellitus (type I and II)
3.Claustrophobic

Study design

Design

Study type: Observational 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):	11-02-2008
Enrollment:	28
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	NL19947.091.07