PET scan imaging for recording brain activity in cochlear implant recipients with tinnitus

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to measure neural activity of the central nervous system in tinnitus related brain areas in cochlear implant recipients with chronic tinnitus and to determine the relation between this neural activity and the subjective tinnitus experience of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Observational invasive

Summary

ID

NL-OMON34253

Source
ToetsingOnline

Brief title
PET-scans of cochlear implant patients with tinnitus

Condition

- Inner ear and VIIIth cranial nerve disorders
- Structural brain disorders

Synonym
noise in the head, tinnitus

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Gratamafonds

Intervention

Keyword: Cochlear implants, PET-scans, Tinnitus

Outcome measures

Primary outcome

The main outcome measure will be the change in cortical activity in cochlear implant recipients who experience subjective improvement of tinnitus by turning the cochlear implant on compared to cochlear implant recipients who do not experience improvement of tinnitus by turning the cochlear implant on.

Secondary outcome

Not applicable.

Study description

Background summary

Tinnitus is the perception of sounds in the absence of a physical sound source. It can only be perceived by the patient himself. The prevalence of tinnitus is 4.4% -20% in the general population and 66-100% in the population of cochlear implant candidates. A key hypothesis in the pathogenesis of subjective tinnitus is that it arises as a response of the central auditory system to peripheral hearing loss. Peripheral hearing loss results in a decrease of afferent input to the brainstem. This may result in an increase of spontaneous neural activity at several levels in the auditory brainstem and cortex, which is believed to potentially cause tinnitus. Previous studies show that cochlear implants have a positive influence on the tinnitus experience in 40-86% of cochlear implant recipients. In this study we will investigate the influence of a cochlear implant on the neural activity in tinnitus related brain areas and see if this corresponds with subjective tinnitus experience of the patients. Positron emission tomography (PET) is an imaging modality that can be used to study neural activity in the human brain and a PET scan can in this way identify mechanisms that underlie the generation of tinnitus in humans. Labelled water (H215O) PET scans are, with a half life time of 2 minutes, the PET scans with the best temporal resolution and are the best type of PET scans for detecting changes in cortical activity. Our hypothesis is that subjective tinnitus inhibition by a cochlear implant is reflected in a decrease of activity of the

central nervous system. This would be confirmed if switching on the implant corresponds to a decrease of H215O PET signals from cortical brain areas.

Study objective

to measure neural activity of the central nervous system in tinnitus related brain areas in cochlear implant recipients with chronic tinnitus and to determine the relation between this neural activity and the subjective tinnitus experience of patients.

Study design

observational case control study

Study burden and risks

The amount of injected radioactive matherial (12 scans of 500 MegaBecquerel (MBq)) results in an amount of radiation of approximatel 5,6 milliSievert (mSv) (International Commission on Radiological Protection 80). In comparison, according to the *Rijksinstituut voor Milieuhygiëne (RIVM)*, the annual radiation dose in the Netherlands in 1.7 mSv. According to the international commission on radiological protection (ICRP) the estimated risk for this scanning procedure is categorised a IIb, minor to intermediate level of risk, 1-10mSv.
No adverse of serious adverse events are to be expected during H215O PET-scanning. The physical discomfort during the scanning procedure is minimal. The subject will be asked to lay quiet in the scanner for 12 times 2 minutes in a dark surrounding with a head immobiliser.
Before and after every scan the patients are asked to rate the loudness of their tinnitus on a scale from 0-10.

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

10 healthy one-sided cochlear implant recipients who experience inhibition of their chronic tinnitus (> 3 months, perceived in the head, constant in presence)by turning the cochlear implant on, age > 18, right handed.
10 healthy one-sided cochlear recipients who do not experience inhibition of their chronic tinnitus (> 3 months, perceived in the head, constant in presence) by the cochlear implant, age >18, right handed.

Exclusion criteria

Presence of any major medical, neurological or psychiatric diagnoses now or in the past, specific epilepsy, severe head injury or previous cranial neurosurgery, participation in a study with radiation exposure in the year prior to this study, radiological workers, use of drugs or medications that reduce cortical excitation such as anticonvulsants, benzodiazepines or other sedatives (e.g. antihistamines), pregnancy.

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-05-2011
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	06-10-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL33216.042.10