PETscan imaging for objectivation of cortical hyperactivity in tinnitus patients

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The primary objective of this study is to objectivate neural hyperactivity at the cortical level of chronic tinnitus sufferers compared to control subjects with the use of FDG-PET-scans.

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

Summary

ID

NL-OMON31403

Source
ToetsingOnline

Brief title
PETscan for chronic 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: NWO

Intervention

Keyword: auditory cortex, Positron Emission Tomography, tinnitus

Outcome measures

Primary outcome

The main study parameter will be the cortical hyperactivity in tinnitus patients compared to control subjects in FDG-PET, analysed with SPM5. Our estimation is that this cortical hyperactivity is localised in the primary auditory cortex and the associative auditory cortex, although other regions might display some hyperactivity as well

Secondary outcome

Not applicable

Study description

Background summary

Approximately 10 to 15% of the general population complains about tinnitus, and 4-5% is severely affected by it. Subjective tinnitus is only perceived by the patient, and can not be objectified by an external observer. It is believed to be the result of plastic changes and reorganization processes in the auditory pathway and brain structures, most likely caused by deprivation of input. Several attempts have been made to register this change of activity in the CNS with imaging studies.
Positron Emission Tomography (PET) scan is an excellent tool for assessment of regional function of the human brain, in a quantitative manner. Until now 16 studies with PET-scanning in tinnitus patients have been performed, only 6 with [18F]deoxyglucose (FDG). FDG-PET scanning reveals base-line metabolism in brain tissue with a labeled biologically important compound without the need for manipulation. Results have not been conclusive due to small sample size, various manipulations or dependency on experimental interventions as a comparison. Our hypothesis is that FDG-PET scanning can be used to determine neural hyperactivity at the cortical level of chronic tinnitus sufferers. This will then provide an objective measurement for subjective tinnitus.

Study objective

The primary objective of this study is to objectivate neural hyperactivity at the cortical level of chronic tinnitus sufferers compared to control subjects with the use of FDG-PET-scans.

Study design

Observational case-control study

Study burden and risks

According to the most recent publication of ICRP (ICRP 80) the total amount of radiation for [18F]deoxyglucose in this scanning procedure is 3.8 mSv. The estimated risk for this scanning procedure is categorised as IIb (ICRP 62), minor to intermediate level of risk, 1-10 mSV. In comparison, according to the *Rijksinstituut voor Mileuhygiëne (RIVM)*, the annual radiation dose in the Netherlands is 1.7 mSv. The number of visits is once for the scanning procedure. The audiometric analysis for control subjects will take place in 1 visit. No adverse or serious adverse events are to be expected during FDG-PET-scanning. The physical discomfort during the scanning procedure is minimal. The subject will be asked to lay quiet in the scanner for fifty minutes in a quiet and dark surrounding with a head immobiliser.

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

Chronic tinnitus, > 3 months, perceived in the head, not lateralized, constant in presence.
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 PET study 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. 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:	Recruiting
Start date (anticipated):	31-01-2008
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

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	NL19448.042.07