

Response of the central auditory system in tinnitus and hearing loss, an fMRI study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hearing disorders
Study type	Observational non invasive

Summary

ID

NL-OMON31748

Source

ToetsingOnline

Brief title

Tinnitus and fMRI

Condition

- Hearing disorders

Synonym

ringing in the ear

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: American Tinnitus Association

Intervention

Keyword: fMRI, Hearing loss, Tinnitus

Outcome measures

Primary outcome

- audiometric test outcomes
- scores of questionnaires
- fMRI response amplitude of auditory and limbic brain areas

Secondary outcome

n.a.

Study description

Background summary

Tinnitus is possibly based on abnormal neural activity of the central auditory system. Earlier research showed that in patients with near-normal hearing the response to sound of the brain was enlarged in comparison to that in subjects without tinnitus.

Study objective

Most patients with tinnitus also have a hearing loss. The primary goal of this study is to investigate whether in patients with hearing loss AND tinnitus, the neural response of the brain is enlarged compared to hearing-impaired patients without tinnitus. In addition, we will investigate whether the response of the brain is related to the severity of tinnitus.

Study design

Patients undergo ENT-investigation, extensive audiometric testing and will complete a number of questionnaires on tinnitus and related fear and anxiety. In addition, fMRI will be carried out, in order to measure the response of the brain to sound. The outcome of the fMRI measurement will be correlated with the outcome of the ENT-investigation, the audiometry and the questionnaires.

Study burden and risks

- There are no known risks associated with the study.
- Patients will spend a total of 340 minutes to this study. Hearing tests and questionnaires will require their concentration.

Contacts

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Healthy subjects, at least 18 years old
- Audiometric tone threshold ≥ 20 dB and ≤ 60 dB for both ears on the octave frequencies 500, 1000, 2000, and 4000 Hz
- Subjects have signed informed consent in accordance with the Dutch legal regulation (Wet

Medisch Wetenschappelijk Onderzoek met Mensen).

- No contradictions for fMRI according to the MRI-checklist

Exclusion criteria

- Presence of any major medical, neurological or psychiatric diagnoses now or in the past.
- Pregnancy
- Claustrophobia
- Epilepsy

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:	Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2008
Enrollment:	100
Type:	Anticipated

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	NL21088.042.07