Neural reorganization in tinnitus: a high-field functional and antomical MRI study

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Hearing disorders
Study type	Observational non invasive

Summary

ID

NL-OMON41097

Source
ToetsingOnline

Brief title
Neural reorganization in tinnitus

Condition

- Hearing disorders
- Cranial nerve disorders (excl neoplasms)

Synonym
phantom sound perception, tinnitus

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,SWOL

Intervention

Keyword: (f)MRI, 7 Tesla, Neural reorganization, Tinnitus

Outcome measures

Primary outcome

The hypothesized link between frequency tuning and tinnitus will be tested by comparing the size and response magnitude of the auditory cortex regions that show tuning to the patient*s specific tinnitus frequency vs. regions that show tuning to the other (non-tinnitus) frequencies. In this way, patients can serve as their own controls, in addition to matching healthy controls. Furthermore, anatomical features (measures of myelin content and cortical thickness) will be assessed in the same regions of interest.

Secondary outcome

Not applicable.

Study description

Background summary

Tinnitus is a hearing disorder that is characterized by the chronic perception of phantom sound. Current therapy forms are either very time-consuming or no more effective than placebo. Therefore development of novel more effective therapies is needed, but this is currently hampered by the lack of understanding the neural basis of tinnitus. The specific goal of the proposed study is to fill this gap by identifying whether tinnitus is accompanied by anatomical and functional changes within the central auditory system. For example, as suggested by animal electrophysiology and explored by recent human neuroimaging research, tinnitus may be accompanied by functional reorganization of frequency tuning: Neurons in the human auditory system are typically tuned (i.e., most sensitive) to specific audio frequencies but after acoustic overstimulation, they may adapt their frequency tuning. Therefore, the proposed study will test whether the ongoing illusory auditory stimulation that is caused by chronic tinnitus leads to adaptations in frequency tuning and

neuroanatomy, i.e., a change in the cortical regions that represent the tinnitus frequency.

Study objective

The general goal of our study is to unravel the anatomical and functional correlates of tinnitus in the human brain using structural and functional magnetic resonance imaging (MRI). We will use a high-field (7 T) MRI scanner and obtain a) detailed information about brain anatomy in the central auditory system and b) measure functional responses in the auditory cortex in order to assess the overall activation level and the tonotopic organization of auditory cortex.

Study design

The study will be an observational fMRI study.

Study burden and risks

The participants will be scanned once for 55 min (excluding breaks). When attention is paid to the contra-indication of an MRI scanner, participation in an MRI experiment at 7 T is harmless. An interview and a audiogram will be performed before scanning (tinnitus patients also fill in a tinnitus questionnaire and undergo a tinnitus spectrum test), which also is harmless and takes approximately 60 min.

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

The main inclusion criteria of the patient groups are:
* Male or female between 18 and 75 years
* Subjective tinnitus (i.e. not caused by an acoustic source inside the head, e.g., vascular abnormalities that cause pulsatile tinnitus)
* Stable tinnitus (i.e., present for at least 8 h per day since more than a year)
* Tinnitus that is dominant within one of three octaves (low: <750 Hz, middle: 750-3000 Hz, high: >3000 Hz; the exact frequency ranges will be determined empirically based on patient availability)
* Patient has not received medical care from an otolaryngologist and is able and willing to undergo the MRI measurements, as indicated by written informed consent.;The main inclusion criteria of the healthy subjects are:
* Male or female between 18 and 75 years
* No tinnitus
* Subject is able and willing to undergo the MRI measurements, as indicated by written informed consent.

Exclusion criteria

Exclusion criteria of the patient groups are:
* Fletcher Index > 50 dB HL for both ears (i.e., mean of hearing loss in decibels for 1k, 2k and 4k Hz)
* Hyperacusis (oversensitivity to sound), phonophobia (defined as a persistent, abnormal, and unwarranted fear of sound), misophonia (dislike of certain sound),
* Neurological-, neurosurgical- and psychiatric history
* Use of dopaminergic drugs since this medication greatly influence the fMRI scans (Haslinger et al., 2001, Mattay et al., 2002)
* Morbid obesitas (BMI > 35) since it cannot be guaranteed that these subjects will fit in the

scanner
* Current treatment of tinnitus and implanted devices or other metal objects that are not suitable for MRI. ;Exclusion criteria of the healthy subjects are:
* Fletcher Index > 50 dB HL for both ears (i.e. mean of hearing loss in decibels for 1k, 2k and 4k Hz)
* Hyperacusis (oversensitivity to sound), phonophobia (defined as a persistent, abnormal, and unwarranted fear of sound), misophonia (dislike of certain sound),
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* Morbid obesitas (BMI > 35) since it cannot be guaranteed that these subjects will fit in the scanner
* Current treatment of tinnitus and implanted devices or other metal objects that are not suitable for MRI.

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:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	30-12-2014
Application type:	First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL49812.068.14