INTERACTIONS BETWEEN AUDITORY AND LIMBIC BRAIN AREAS IN TINNITUS

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

Summary

ID

NL-OMON33253

Source
ToetsingOnline

Brief title
BRAIN INTERACTIONS IN TINNITUS

Condition

- Hearing disorders
- Neurological disorders NEC
- Disturbances in thinking and perception

Synonym
ringing in the ear

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: NWO-VENI-016.096.011

Intervention

Keyword: Central Auditory System, Connectivity, fMRI, Tinnitus

Outcome measures

Primary outcome

Audiometric and psychometric values obtained in a diagnostic protocol, and

stimulus-evoked as well as spontaneous BOLD fMRI signals in the brain.

Secondary outcome

not applicable

Study description

Background summary

Tinnitus is a prevalent hearing disorder that affects millions of people and has a severely disabling impact on life in about 1-3% of the general population. It is characterized by the perception of sound in the absence of any external sound sources. An increasing amount of evidence suggests that tinnitus is generated as a result of pathological spontaneous activity in the brain. In addition to auditory brain regions, the limbic system that processes emotions is thought to be involved in the underlying mechanism. Neuroimaging studies on tinnitus have so far mainly focused on sound-evoked responses in the classical auditory brain centers only. They have neither investigated spontaneous fluctuations in brain activity, nor addressed the functional relationships with other brain areas like the limbic system.

Study objective

The current study employs functional magnetic resonance imaging (fMRI) to investigate the auditory and limbic areas in tinnitus patients by means of innovative analysis methods that permit the assessment of functional interactions between brain areas. Because these methods do not rely on the presentation of external sound stimuli and are able to study inherent spontaneous activity of the brain, they offer a unique opportunity in the context of a disorder like tinnitus, in which a phantom sound percept is generated intrinsically. The study will include tinnitus subjects and matched controls. Functional MRI experiments will be performed using novel paradigms that include the presentation of a variety of sound stimuli as well as

so-called resting state measurements. The analysis of the fMRI data will focus on the primary hypothesis that the interaction between the limbic and the auditory system is abnormal in tinnitus patients. The outcome of this study is expected to be of key importance to our understanding of tinnitus.

Study design

Two-group exploratory study.

Study burden and risks

The clinical diagnostic tests involve ENT-investigation, several audiometric tests, and the administration of questionnaires (~4 hours.). A single fMRI scanning session will take place on a separate day (~2 hours). None of the procedures expose the subject to known risks.

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

No reported tinnitus (control group) / Mild to moderate subjective tinnitus with THI-score of 18-56 (patient group)
Adult (18-60 yrs.)
No medical, neurological, or psychiatric disorders (excluding tinnitus)
Normal hearing to moderate symmetrical hearing loss (<60 dB at 500-2000Hz)
No contraindications for fMRI

Exclusion criteria

Non-compliance with inclusion criteria

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):	03-02-2010
Enrollment:	60
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
Other	Nederlandse Onderzoek Databank nummer OND1331679
CCMO	NL27590.042.09