fMRI and Brainstem Evoked Response Audiometry (BERA) to Probe the Mechanism of Human Brain Auditory System in Tinnitus and Unilateral Hearing Loss

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

Summary

ID

NL-OMON52331

Source
ToetsingOnline

Brief title
fMRI and BERA for tinnitus and unilateral hearing loss

Condition

- Hearing disorders

Synonym
Ringing in the ear

Research involving
Human

Sponsors and support

Primary sponsor: Keel-, Neus- en Oorheelkunde
Source(s) of monetary or material Support: European Union Horizon 2020

Intervention

Keyword: BERA, fMRI, Tinnitus, Unilateral hearing loss

Outcome measures

Primary outcome

The main endpoints are differences between response characteristics associated with unilateral hearing loss and the presence of tinnitus. These differences are quantified as differences between the tonotopic map of the auditory cortex between the subject groups. Tonotopic maps are based on the MRI acquisitions.

Secondary outcome

A second study parameter is a difference in BERA peak amplitudes and latencies between the groups.

Study description

Background summary

Ringing in the ear or tinnitus is a hearing disorder, defined as phantom sound perception without any external sound source. The loudness of tinnitus is different in different persons, and in severe cases, it can negatively affect the person*s life.
Tinnitus probably originates from functional changes in the brain auditory system. Animal experiments have reported such changes in the brainstem in animals with induced tinnitus. There is also a strong hypothesis which links tinnitus to hearing loss. Earlier studies suggest that there are differences in the functional changes between unilateral and bilateral hearing loss, and that these may lead to tinnitus via different pathways. The current study will test functional differences between subjects with unilateral hearing loss, and subjects with and without tinnitus.
We are going to investigate the human brain in a highly informative manner,

using a state-of-the-art zoom-fMRI. The measurement will be combined with brainstem evoked response audiometry (BERA), the standard clinical tool to assess the auditory response from the brainstem.

Study objective

By acquiring functional MR images and brainstem evoked response audiometry (BERA) from the auditory nuclei in the human brainstem, we expect to observe neurofunctional differences between the subjects with unilateral hearing loss, and subjects with and without tinnitus.

Study design

This is an exploratory case-control study in which four groups of human subjects are compared. This study design allows us to disentangle the contributions that unilateral hearing loss and tinnitus have to functional changes in the brain auditory pathway, respectively.

Study burden and risks

Each participant is asked to fill in a number of questionnaires regarding handedness, MRI compatibility, and hyperacusis. Also, tinnitus patients fill in questionnaires regarding their tinnitus. The questionnaire part takes 30 minutes in total. Then, using clinical audiometry, we measure the hearing thresholds of the subject and perform a loudness matching task to determine stimulus levels to be used in subsequent MRI sessions. The tinnitus pitch will also be measured. This takes 50 minutes. The functional MRI session via a 3-Tesla MRI scanner takes 75 minutes. Also, the auditory brainstem response measurement takes 40 minutes. None of the procedures has a known benefit or risk for the participant.

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

To be eligible to participate in this study, the subject
- must have in the age range of 18-80 years old.
- Audiogram: [35 dB =< (pure tone average in 2, 4, and 8 kHz) =< 65] for one ear and audiogram [(pure tone average in 2, 4, and 8 kHz) < 30] for the other ear, if the subject is in one of the unilateral hearing loss groups.
- Audiogram: [(pure tone average in 2, 4, and 8 kHz) < 30] for both ears, if the subject is in one of the groups with no hearing loss.
- Audiogram: [(pure tone average in 0.25 0.5, and 1 kHz) < 30] for both ears, for all the subjects

Exclusion criteria

- Non-conformance to any of the inclusion criteria.
- Contraindication for MRI according to the MRI checklist.
- Reported medical, neurological, or psychiatric disorders (excluding tinnitus and hearing loss).
- Using hearing aids

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-02-2022
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	07-02-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	28-08-2023
Application type:	Amendment
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	NL79002.042.21