Focused fMRI and Brainstem Evoked Response Audiometry (BERA) to Probe the Brainstem Mechanism in Tinnitus

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

Summary

ID

NL-OMON48145

Source
ToetsingOnline

Brief title
Focused fMRI and BERA for tinnitus

Condition

- Aural disorders NEC

Synonym
Ringing in the ears

Research involving
Human

Sponsors and support

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

Intervention

Keyword: BERA, Brainstem, Focused fMRI, Hearing loss, Tinnitus

Outcome measures

Primary outcome

The main endpoints are differences between response characteristics associated with hearing loss laterality and the presence of tinnitus. These differences include the difference in the response amplitudes of various brainstem nuclei as assessed by fMRI, BERA and, tonotopic maps as assessed by MRI.

Secondary outcome

n.v.t

Study description

Background summary

The tonotopic map of the brain auditory area represents the neurofunctional organization, the localization of the neurons tuned to each frequency band. In the animals and humans with induced tinnitus, the tonotopic map of the cortex is changed. The functional organization of the cortex deviates in animals with induced tinnitus (Engineer et al. 2011). Also, a recent study (Koops et al. 2019) suggests that higher frequencies are dominant in the tonotopic map of humans with bilateral hearing loss. This result differs from an animal study which reported an overrepresentation of lower frequencies in animals with unilateral hearing loss. Linking the results from the literature not only implies that hearing loss plays an influential role in neuroplasticity, but also the laterality of hearing loss might have a significant impact. Therefore, in this study, we compare the neural function of the human brainstem in subjects with unilateral hearing loss, bilateral hearing loss, and presence tinnitus, and we expect to observe a difference across the groups. Also, we include subjects without hearing impairment (as the controls) for comparison to the other groups.

Study objective

The main objective of this study is to compare the brainstem sound-evoked

response of the subject groups with different hearing loss laterality and with/without tinnitus. These comparisons may let us know if the function of the human brainstem is different in unilateral hearing loss, bilateral hearing loss, and tinnitus.

Study design

This is an exploratory case-control study in which six groups of human subjects are compared. This study design allows us to disentangle the contributions that hearing loss and tinnitus have to functional changes in the brainstem, 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. This takes 50 minutes. The functional MRI session via a 3-Tesla MRI scanner takes 60 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 be in the age range of 18-80 years old.
- must have a hearing threshold of both ears between 40 dB and 60 dB, if he/she is in one of the bilateral hearing loss groups.
- must have a hearing threshold between 40 dB and 60 dB for one ear, and the normal hearing threshold, less than 20 dB, for the other ear, if he/she is in one of the unilateral hearing loss groups.
- must have a hearing threshold of less than 20 dB for both ears, if he/she is in one of the normal threshold groups.

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).

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):	10-03-2020
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	12-08-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	27-01-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-06-2023
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	NL69189.042.19