

Visualizing tinnitus with EEG.

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Primary objective of the study: To find out which areas in the brain play a part in the maintenance of tinnitus, and what the roles of those areas are. This will be done using the AEP response in EEG recordings. Secondary objectives of the study: 1. To...

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

Summary

ID

NL-OMON35893

Source

ToetsingOnline

Brief title

Visualizing tinnitus with EEG.

Condition

- Aural disorders NEC
- Neurological disorders NEC

Synonym

ringing in the ears

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Twente

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: EEG, neuromodulation, tinnitus

Outcome measures

Primary outcome

The primary EEG study parameters are the latency (in milliseconds) and amplitude (in microvolts) of the N100 component of the AEP response. The study parameters will be compared between the three study groups.

Secondary outcome

The secondary study parameters are the latency (in milliseconds) and amplitude (in microvolts) of the N200 and P300 components of the AEP response in the EEG recordings. The frequency spectrum of the brain activity is also a study parameter. The study parameters will be compared between the three study groups.

Study description

Background summary

Tinnitus is often defined as the perception of a tone without the presence of an external stimulus. About 10% of the western adult population suffers from tinnitus and in about 1% of the population the tinnitus strongly affects their life. Neuromodulation is a promising treatment for tinnitus, but is not used in the Netherlands so far. In order for neuromodulation to be successful it should be clear in what brain regions the tinnitus is generated and what the activity in those regions is. However, the pathophysiology of tinnitus is still greatly unknown. Therefore, in this study the activity in brain areas that are suspected to generate the tinnitus sound will be visualized with EEG. The focus with the EEG measurements will be on the auditory cortex.

Study objective

Primary objective of the study:

To find out which areas in the brain play a part in the maintenance of tinnitus, and what the roles of those areas are. This will be done using the AEP response in EEG recordings.

Secondary objectives of the study:

1. To find out if there are changes in the parameters of the AEP components in the EEG recordings in tinnitus patients.
2. To assess the theoretical potential of neuromodulation as a therapy for tinnitus.

Study design

This is a case-control observational study comparing processing of sound in tinnitus patients with normal hearing subjects and with hearing impaired non-tinnitus subjects.

Study burden and risks

Participating subjects are asked to fill out two questionnaires which will take about 15 minutes. Furthermore they are asked to travel to the Clinical Neurophysiology department of the Medisch Spectrum Twente once. There they will undergo an EEG scan with a duration of about 25 minutes. The total duration of the study for each participating subject will be 1 hour (including preparation time). There is no individual benefit for the subjects participating in the study.

There are no risks associated with the study, nor are there any harmful aspects with respect to participating.

Contacts

Public

Universiteit Twente

Postbus 50000
7500 KA Enschede
NL

Scientific

Universiteit Twente

Postbus 50000
7500 KA Enschede
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

General:

- Men and woman;

Tinnitus patients:

- Tinnitus perception for more than 1 year
- Perception of a tone
- Unchanged tinnitus perception (pitch, amplitude) for more than 6 months

Hearing impaired non-tinnitus subjects:

- Perceptive hearing impairment

Exclusion criteria

General:

- Age < 18 years
- Ear inflammation
- Other ear diseases like acoustic neuroma
- Diagnosed neurological or psychiatric disease
- Conductive hearing impairment.

Tinnitus patients:

- Perception of noise
- Pulsatile tinnitus

Normal hearing subjects:

- Conductive hearing impairment
- Use of hearing aids
- (history of) Menière's disease
- (history of) tinnitus perception

Hearing impaired non-tinnitus:

- Conductive hearing impairment
- (history of) Menière's disease
- (history of) tinnitus perception

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):	12-05-2011
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO	
Date:	30-03-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)

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	Wordt gedaan na goedkeuring van METC Twente
CCMO	NL35949.044.11