Exploring the response characteristics of the human vestibulocochlear nerve.

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Determining a response characteristic of the vestibulocochlear nerve in healthy subjects (e.g. subjects without hearing loss or tinnitus), for the benefit of assessing possible aberrant characteristics in subjects with tinnitus, which data could be...

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

Summary

ID

NL-OMON46339

Source
ToetsingOnline

Brief title
Characteristics of the cochlear nerve.

Condition

- Aural disorders NEC

Synonym
tinnitus; ringing in the ear

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cochlear nucleus, direct recording, responses, vestibulocochlear nerve

Outcome measures

Primary outcome

Response characteristics of the vestibulocochlear nerve, such as latency,

amplitude and morphology.

Secondary outcome

N/a.

Study description

Background summary

Tinnitus is a condition for which the pathophysiology is unclear. There are however a number of putative mechanisms that could explain the cause for (the onset of) tinnitus. It is thought that the cochlear nucleus - as part of the vestibulocochlear nerve - has a role in tinnitus-generating signals. The aim of this study is to determine the response characteristics of the vestibulocochlear nerve in healthy subjects (i.e. patients without hearing loss or tinnitus), in order to assess possible aberrant functioning of this structure in patients with tinnitus in future research projects.

Study objective

Determining a response characteristic of the vestibulocochlear nerve in healthy subjects (e.g. subjects without hearing loss or tinnitus), for the benefit of assessing possible aberrant characteristics in subjects with tinnitus, which data could be gathered in future research projects.

Study design

This is an observational study. Patients undergoing the Jannetta procedure at the UMCG, who have normal hearing (PTA <= 30 dBnHL) and who do not suffer from tinnitus are included in this study.

During the Jannetta procedure, the vestibulocochlear nerve is exposed. The recording electrode is placed on this structure, and the responses to differing

external stimuli are recorded. The external stimuli are provided by insert earphones, connected to an ABR system, and will range in intensity levels, rate, stimulus type and presence or absence of masking noise.

Study burden and risks

Before surgery, two tests are performed on a participant. An audiogram is made and an ABR test is performed. These tests will take 60 minutes of time. The actual research measurements take place during the surgery, so patients will not suffer any burden from these measurements. None of the procedures expose the participants to known risks.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Scheduled for a Jannetta procedure at the department of Neurosurgery;
- adult, aged 18 years or older;
- hearing threshold is smaller than or equal to 30 dBHL.

Exclusion criteria

- Non-conformance to any of the inclusion criteria;
- reported suffering from any type of tinnitus.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-03-2017
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Subdural bipolar recording electrode
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	24-01-2017

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	23-11-2017
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	NL58280.042.16