The ocular Vestibular Evoked Myogenic Potentials (oVEMPs) in patients with otosclerosis

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To gain information about the characteristics of the oVEMP-response in patients with otosclerosis and to objectify the complaints of dizziness pre- and postoperatively through a dizziness questionnaire.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Middle ear disorders (excl congenital)
Study type	Observational non invasive

Summary

ID

NL-OMON34883

Source
ToetsingOnline

Brief title
oVEMP-test in otosclerosis

Condition

- Middle ear disorders (excl congenital)

Synonym
dizzyness, otosclerosis, vertigo

Research involving
Human

Sponsors and support

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

Intervention

Keyword: diagnostics, otolith organs, otosclerosis, oVEMP

Outcome measures

Primary outcome

The main study parameters are the amplitude and the threshold of the oVEMP-response.

Secondary outcome

Other characteristics of the oVEMP-response which will be studied are the latencies of the various peaks in the response. All variables will be studied in relation to the level of the oVEMP-evoking stimulus. The final variable that will be studied is the dizzyness questionnaire (Dizzyness Handicap Inventory) pre- and postoperatively.

Study description

Background summary

In patients with otosclerosis hearing loss is the main complaint, but some patients complain of dizziness. The location of the diseased bone in otosclerosis at the stapes footplate is in close proximity to the otolithic organs, and surgery is also performed at this specific location. The original disease and the surgery itself could influence the function of the otolithic organs. Because the oVEMP-test is a way of testing the otolith function possible differences in oVEMP-response in otosclerosis patients will be compared to our clinical standard.

Study objective

To gain information about the characteristics of the oVEMP-response in patients with otosclerosis and to objectify the complaints of dizziness pre- and postoperatively through a dizziness questionnaire.

Study design

A cohort of patients with otosclerosis will be tested and the results will be compared to our clinical standards (20 healthy volunteers).

Study burden and risks

For this study patients will have to visit the UMCU twice for the oVEMP-test. Each visit will take less than two hours, thus for the complete study this will be less than four hours. For the oVEMP-test 5 electrodes will be placed on the face of the patient and a bone-conducted stimulus will be delivered to the patient in supine position with raised eyes. The potentials risks of the oVEMP-test are very small. The bone-conducted stimulus can be experienced as uncomfortable, but is not painful and will not damage the auditory system.

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

Otosclerosis with indication for stapedectomy
Age >= 18 years

Exclusion criteria

An interfering cause of vertigo
History of eye-motility disorders

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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-03-2010
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Toennies Multiliner evoked potential recording system & Bruel&Kjaer Mini-shaker type 4810
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	05-02-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL31051.041.09