The ocular Vestibular Evoked Myogenic Potentials (oVEMPs) in patients with Meniere's disease.

No registrations found.

Ethical review Positive opinion **Status** Recruiting

Health condition type -

Study type Interventional

Summary

ID

NL-OMON27017

Source

Nationaal Trial Register

Brief title

N/A

Health condition

Meniere's disease

Sponsors and support

Primary sponsor: University Medical Center Utrecht

Source(s) of monetary or material Support: University Medical Center Utrecht

Intervention

Outcome measures

Primary outcome

To gain information about the characteristics of the oVEMP-response in patients with Menière's disease.

Secondary outcome

To evaluate the clinical applicability and especially the perceived burden of the oVEMP-test.

Study description

Background summary

Menière's disease still poses a diagnostic and therapeutic problem. Currently Menière's disease is diagnosed according to clinical criteria by the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) 1995. These criteria are two or more episodes of vertigo, longer than 20 mins, perceptive hearing loss, tinnitus or aural fullness and exclusion of alternative causes of the complaints. Menière's disease is accompanied by endolymphatic hydrops which probably inflicts damage to the cochlea and the vestibular organ. Current standard vestibular testing (Electronystagmography (ENG)) solely tests the function of one of the five subcomponents of the vestibular organ, the horizontal semicircular canal. In Menière patients the ENG shows variable responses and in many cases this test is normal. An additional vestibular test, the ocular Vestibular Evoked Myogenic Potential (oVEMP) test, can be used to evaluate the function of two other subcomponents, the two otolith organs. In this study we will compare the oVEMP responses of Menière patients to responses in normal subjects.

Study objective

In patients with Meniere's disease an altered of absent oVEMP-response is seen.

Study design

01-03-09: Start of study.

Intervention

oVEMP-test.

For the oVEMP-test 5 electrodes will be placed on the face of the patient and an acoustic stimulus will be delivered to the ears with the patient in supine position with raised eyes. The main study parameter is the amplitude and threshold of the oVEMP-response, which will be compared to our clinical standard.

Contacts

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Eligibility criteria

Inclusion criteria

- 1. Uni- or bilateral Meniere's disease according to the criteria of the AAO-HNS 1995;
- 2. Age older 18 years.

Exclusion criteria

- 1. An interfering cause of vertigo;
- 2. History of eye-motility disorders;
- 3. Audiometrically defined conductive hearing loss of more than 20 dB NHL at 500 Hz.

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation: Non controlled trial

Control: N/A, unknown

Recruitment

NL

Recruitment status: Recruiting
Start date (anticipated): 01-03-2009

Enrollment: 40

Type: Anticipated

Ethics review

Positive opinion

Date: 23-02-2009

Application type: First submission

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

NTR-new NL1601 NTR-old NTR1681 Register ID

Other METC UMC Utrecht: 08-388

ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A