Measuring Vestibulo-Ocular Reflex in three dimensions

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Observational non invasive

Summary

ID

NL-OMON40409

Source
ToetsingOnline

Brief title
Measuring Vestibulo-Ocular Reflex in 3D

Condition

- Inner ear and VIIIth cranial nerve disorders
- Nervous system neoplasms benign
- Nervous system, skull and spine therapeutic procedures

Synonym
Acoustic Neuroma, Vestibular Schwannoma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: eye movements, three-dimensional, vertigo, vestibular system

Outcome measures

Primary outcome

Experiment 1: The determination of the reference range of the VOR in different

methods

Experiment 2: The difference in gain and misallignement of the VOR; before and

after treatment.

Experiment 3: The effect of head angle on the gain and misalligment of the VOR.

Secondary outcome

not applicable

Study description

Background summary

The vestibular system is important in everyday life. The three semi-circular canals regulate compensatory eye movements, equal and opposite to head movement to reserve the gaze. This is called the Vestibulo-Ocular Reflex, or VOR. Damage of this system, as with a Acoustic Neuroma, may cause dizziness, unsteadiness of gait and vertigo.
Current methods for evaluating vestibular impairment are quick, easy to do and non-invasive. A disadvantage however is the fact that only the horizontal canals are examined. Moreover, the rotational chair test measures the VOR only at low frequencies and patients describe the caloric test as aggravating.

Study objective

The objective of this study is to examine the vestibular system in three dimensions. To achieve this goal three experiments are performed. The EyeSeeCam video-oculography is validated with the scleral search coils (international golden standard). Using these glasses, new vestibular function tests used in the clinic can be validated. Experiments 2 and 3 are more fundamental, for which the scleral search coil is used to measure the VOR in three dimensions.

In experiment 2 the three dimensional VOR is mesasured in patients with an untreated unilateral acoustic neuroma.
And in the third experiment, we want to measure the three dimensional VOR during rotations at different angles of the head, including the angle at which the horizontal canals are equal to earth's horizontal.

Study design

The VOR will be measured in three experiments:
Experiment 1 is an observational study in which the VOR of healthy subjects and patiënts with vestibular impairment are tested using Video-Oculography.
Experiment 2 is a prospective study in which the VOR of patients with unilateral acoustic neuromas are measured in three dimensions using scleral search coils.
Experiment 3 is an observational study, in which the VOR is tested in healthy subjects in three dimension using scleral search coils. The subjects will be measured in 5 different angles of the head.

Study burden and risks

Experiment 1: The patients and healthy subjects are measured for 15 minutes. Different clinical methods will be performed using the Video-Oculography. The experiment will be planned right before or after the hospital appointment.

Experiment 2: The patients are measured twice (before and after treatment) during half an hour. With all preperations the appointment will take about two hours both times. Before the scleral search coil is applied, the eye will be anaesthetized using oxybuprocaïne-eyedrops.

Experiment 3: The healthy subjects are measured once during an appointment of two hours. The five different angles are measured during half an hour. Before the scleral search coil is applied, the eye will be anaesthetized using oxybuprocaïne-eyedrops.

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

Absence of neurological disease and complaints of vertigo (except for the acoustic neuroma which is present at the patientgroup), no drugs or alcohol abuse 6 months prior to the study, no history of 'closed head injury', age above 18 years and a signed informed consent.

Exclusion criteria

Neurological or psychiatric disease, vertigo complaints, drugs or alcohol abuse less than 6 months prior to the study, history including 'closed head injury', underaged (< 18 years)

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:	Will not start
Enrollment:	111
Type:	Anticipated

Ethics review

Approved WMO

Date:	24-01-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL46573.078.13