Measurement of vestibular function and balance of patients with Vestibular Schwannoma. - A feasibility study -

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Observational non invasive

Summary

ID

NL-OMON31746

Source
ToetsingOnline

Brief title
Vestibular function and balance measurement.

Condition

- Inner ear and VIIIth cranial nerve disorders

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: Balance, Feasibility, Vestibular function, Vestibular Schwannoma

Outcome measures

Primary outcome

Feasibility of a moving platform to measure vestibular function, and

accelerometry and an insole pressure device to measure balance of patients with

vestibular schwannoma.

Vestibular function: 3D motion platform

Balance: Berg balance scale, accelerometry, insole pressure device

Secondary outcome

Patient characteristics (e.g. age, gender) and disease characteristics (e.g.

tumor size) will be registered.

Study description

Background summary

Vestibular lesions lead to balance problems and vertigo. This has a major influence on the patient*s daily functioning. It is estimated that 40% of people older than 40 years have balance problems and vertigo of which 35-55% have a peripheral vestibular lesion. Although vestibular rehabilitation is recommended to facilitate recovery, the therapy effect shows large differences between the patients with vestibular lesions. A possible reason for these differences in therapy effect could be that current clinical vestibular function and balance tests can not discriminate properly between patients that recover full, less or not at all after receiving vestibular rehabilitation. A solution might be to use more advanced techniques to measure vestibular function and balance. Before this, we have to know whether it is feasible to

use these techniques on patients with vestibular lesions.

Study objective

The objective of the study is to determine if a 3D motion platform (to measure vestibular function) and accelerometry and a insole pressure system (to measure balance) can be used in future research on patients with vestibular lesions.
For this, we evaluate the feasibility and discriminative value of these measurement techniques.

Research questions:
1. Is it feasible to measure the vestibular function with a 3D motion platform, and balance with accellerometry and an insole pressure system of patients with a vestibular schwannoma?

2. Can a 3D motion platform, regarding vestibular function, and accellerometry and an insole pressure system, regarding balance, discriminate better than current clinical tests between a) healthy persons and patients with an vestibular lesion and b) between different patients with an vestibular lesion?

Study design

It is a cross-sectional study design. Five patients with vestibular schwannoma and balance problems receiving radiation therapy and 5 healthy controls are selected to participate. Vestibular function is measured by a moving platform, and balance is measured by accelerometry and an insole pressure device. The feasibility to perform these measurements is evaluated by questionnaires for the participants and the researchers. All measurements are performed once.

Study burden and risks

The vestibular and balance tests are not painful or harmfull.

For the vestibular test, contact lenses are placed on the eye with a drop of mimins (oxybuprocaine). 25 years of experience exists with this procedure. Vertigo elicit by the vestibular test with the movement platform dissapears soon after this test.

During the balance measuremenets, patients are continuously watched by a researcher or therapist. The risk of falling is, therefore, negligible.
Patients with severe balance problems do not perform balance tests with their eyes closed.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040
3000 CA Rotterdam
Nederland
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040
3000 CA Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- patients with vestibular schwannoma
- vertigo
- balance problems
- no cerebellar problems
- written informed consent

Exclusion criteria

- patients with vestibular schwannoma who receive other treatment than radiation
- heart disorders
- pregnancy

- not understanding the Dutch language

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:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2008
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	18-07-2008
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	NL20322.078.08