Daily functioning in patients with vestibular hypofunction: course and related factors.

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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-OMON50790

Source
ToetsingOnline

Brief title
Daily functioning in patients with vestibular hypofunction

Condition

- Inner ear and VIIIth cranial nerve disorders

Synonym
unilateral and bilateral vestibular hypofuncion, Vestibulopathy

Research involving
Human

Sponsors and support

Primary sponsor: Gelre Ziekenhuizen
Source(s) of monetary or material Support: Gelre Ziekenhuizen

Intervention

Keyword: course, physical activity, vestibular hypofunction, vestibular rehabilitation

Outcome measures

Primary outcome

The primary study parameter is the number of minutes spend on physical activity per day as measured with the MOX Physical Activity Monitoring Sensor (MOX1).

Secondary outcome

Secondary study parameters are fatigue, perceived handicap due to dizziness, balance confidence, patients specific complaints, level of visual vertigo, avoidance of specific movements due to dizziness and/or unsteadiness and the level of perceived recovery.

Study description

Background summary

The consequences of vestibular weakness in patients with vestibular hypofunction are divers and therefore difficult to measure with a single questionnaire or performance test. In patients who experience dizziness and disequilibrium it is likely that this results in a decrease of physical activities which is a disadvantageous for the patient*s recovery. Therefore, it is important to gain more insight in the level and the course of physical activities in patients with vestibular hypofunction. Another frequent complaint in these patients t is fatigue. Nevertheless, fatigue has not been a focus in clinical guidelines nor in vestibular research. Because of the diversity of the complaints seen in patients with vestibular weakness and the current lack of published research on this topic, we aim to get more insight in the course of daily functioning, specifically in physical activity and fatigue.

Study objective

The primary objective is to investigate the course of limitations in physical activity and daily functioning in patients who are diagnosed with unilateral or bilateral vestibular hypofunction, and to identify factors that are associated

with this course. Secondary objectives are to investigate the presence and course of fatigue in patients who are diagnosed with unilateral or bilateral vestibular hypofunction and to assess the association between fatigue, severity of dizziness, physical activity and dizziness related limitations in daily functioning in these patients

Study design

A 6-month prospective, single-centre, observational cohort study.

Study burden and risks

If patients consent to enter the study, they will be invited to wear the MOX1 activity monitor for 7 days/24 hours a day at three time points (i.e. baseline, 3 months, 6 months). In addition the included patients will be asked to fill in seven questionnaires at baseline, seven questionnaires at 3 months, and eight questionnaires at 6 months follow-up. Estimated time to fill in the questionnaires is 30 minutes. No other procedures will be performed for the study (i.e., no invasive procedures, clinical tests, laboratory tests, etc.).

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

- age 18 years or older
- patients at the Apeldoorns Dizziness Center
- diagnosed with unilateral or bilateral vestibular hypofunction

Exclusion criteria

- age <18 years
- not being able to weare the activity monitor at the upper leg en/or able to walk

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-11-2021
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	15-10-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL77986.058.21