Measurement of balance in a natural environment.
- A validity, reliability and feasibilty study.-

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To assess the validity, reliability and feasibility of accelerometers and the Pedar Mobile system for measuring balance during standing and walking of patients with neurological and vestibular disorders.

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

Summary

ID

NL-OMON32012

Source
ToetsingOnline

Brief title
Balance measurement in a natural environment

Condition

- Middle ear disorders (excl congenital)
- Movement disorders (incl parkinsonism)
- Vascular haemorrhagic disorders

Synonym
balance disorder, Cerebrovascular accident, stroke; Parkinson; cerebellar ataxia; vestibular hypofunction

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Fonds NutsOhra

Intervention

Keyword: ambulatory measurement, balance, reliability, validity

Outcome measures

Primary outcome

Validity and reliability of balance measurement:

- Center of pressure

- Body sway

Secondary outcome

not applicable

Study description

Background summary

Balance impairments, which are common in persons with CVA, Parkinson's disease, cerebellar ataxia, or vestibular disorders, and in elderly people, are a major problem because it reduces the person's mobility and self-efficacy. The importance of measuring balance is fourfold: 1) to get a good diagnosis, 2) to evaluate therapy, 3) to evaluate the progress of a disease, and 4) as a therapeutic tool. Current instruments to asses balance, i.e. clinical tests and laboratory equipment, have their limitations by being subjective and imprecise, or complex and expensive and restricted to a laboratory environment. Insole pressure devices and accelerometers are two new promising techniques to measure balance objectively and in a person's natural environment. Although current studies emphasize the potential of these techniques to measure balance, their validity and reliability to measure balance of patients with neurological and vestibular disorders has not been evaluated.

Study objective

To assess the validity, reliability and feasibility of accelerometers and the

Pedar Mobile system for measuring balance during standing and walking of patients with neurological and vestibular disorders.

Study design

It is a validity study. Ten patients with CVA, 10 with Parkinson's disease, 10 with cerebellar ataxia, 10 with a vestibular disorder, and 10 helathy controls are selected to participate. Balance is measured by accelerometry and an insole pressure device. The feasibility to perform these measurements is evaluated by questionnaires. All measurements are performed at the same day.

Study burden and risks

To measure balance with accelerometers, two sensors (1 x 1 x 1 cm) are placed on the thorax of the subject which are connected with wires to a data recorder (15 x 9 x 3,5 cm; 500 gram) which is worn on a belt around the waist.
To measure balance with the Pedar Mobile system, the subject wears a data recorder (4,5 x 10,5 x 17,5 cm; 750 gram) which is worn in a custom made vest, and insoles (2mm thick) are placed inside the shoes of the subject.
Questionnaires are used to assess the feasibility of the balance instruments.

The balance measurements are not painfull or dangerous. One or two researchers/therapists will stand/walk beside the patient during the balance measurements to minimize the risk of falling. Patients with severe balance problems do not perform the measurements with eyes closed. The measurements have a low physical strain.

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

- 18 years and older
- capable of standing and walking without walking aids
- written informed consent

Exclusion criteria

- a history of neurological disorders other than CVA, Parkinson, cerebellar ataxia
- a neglect
- dementia
- poor vision
- musculoskeletal disorders that influence the lower extremities

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2008
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	02-07-2008
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	NL21819.078.08