validity, measurement feasibility and reliability in geriatric outpatients

Published: 14-10-2019
Last updated: 10-04-2024

To assess the clinical feasibility, reliability and validity of the combined barocontrol PPG-NIRS-ECG monitor.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON48198

Source
ToetsingOnline

Brief title
Barocontrol monitoring

Condition

- Other condition

Synonym
Orthostatic hypotension; fainting

Health condition

Aandoeningen van de bloeddrukregulatie

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: Stichting Technische Wetenschappen;grant

nr 14901

Intervention

Keyword: baroreflex, cerebral autoregulation, orthostatic hypotension

Outcome measures

Primary outcome

- Baroreflex sensitivity and cerebral autoregulation in patients with symptoms, compared between those with and without OH

- Baroreflex sensitivity and cerebral autoregulation in patients with OH, compared between those with and without symptoms

- Collinearity between individual BRS, CAR and orthostatic BP drop magnitude measurements, separate for the three patient groups

Secondary outcome

- Accuracy of PPG based OH classification, separate for the three patient groups.

- The Pearson correlation of PPG based BP estimation with the gold standard Finapres BP measurement between 0-30 seconds after standing up.

- Patient reported convenience, using 1-10 scale.

- The intraclass correlation coefficient of repeats of the same postural change in the same individual.

Study description

Background summary

Orthostatic hypotension (OH) is a systolic blood pressure drop (BP) of more than 20 mmHg and/or a diastolic BP drop of more than 10 mmHg after standing up,

with a prevalence of 20-50% in geriatric outpatients. It is associated with clinical symptoms of light-headedness and dizziness, and poor clinical outcome, such as impaired physical performance, falls and mortality. However, the relationship between OH and clinical symptoms is not always present on the individual level, potentially due to the time-varying magnitude of posture-related BP drops within individuals, and also due to differences in the efficacy of physiological compensatory systems between individuals, such as baroreflex sensitivity (BRS, i.e. increased heart rate as a response to a blood pressure drop)1 and cerebral autoregulation (CAR, i.e. cerebral artery vasodilation as a response to a blood pressure drop to keep cerebral blood flow constant). BRS and CAR function may therefore discriminate between patients with and without symptoms in patients with OH. BRS and CAR should be measured unobtrusively using portable devices to allow for longer term (e.g. 24 hour) measurements to capture the time-varying nature of these systems during postural changes and movement. A custom made combined barocontrol monitor consisting of finger plethysmography (PPG), near-infrared spectroscopy (NIRS), ECG and an accelerometer/ gyroscope was made to this end and demonstrated to produce sensitive and reliable results in young and older healthy adults. However, its validity, measurement feasibility and reliability in geriatric outpatients needs to be addressed.

Study objective

To assess the clinical feasibility, reliability and validity of the combined barocontrol PPG-NIRS-ECG monitor.

Study design

cross-sectional study

Study burden and risks

The extent of burden is limited, consisting of one hour of extra time during a regular clinical visit to the VUmc. This visit will be part of a geriatric assessment that is part of daily clinical care. Test conditions comprise postural changes (standing up from sitting and supine position at different speeds). The different devices used for the blood pressure (Finapres Nova), NIRS and PPG measurements are all non-invasive and unobtrusive, being placed primarily at the forehead, the chest and left arm. The Finapres Nova is CE approved for clinical use. The NIRS-PPG-ECG combination is not CE approved, but has low risk, as described in the attached investigational medical device dossier.

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: between 70 and 90 years
* Cognitive score as clinically assessed using Mini Mental State Examination (MMSE): > 21 points out of 30.

Exclusion criteria

Patients with the following conditions preventing them from performing the test conditions will be excluded:
* Body mass index (BMI) > 35
* Neurological diseases causing inability to walk unassisted
* Musculoskeletal

o immobilization for 1 week during the last 3 months
o orthopedic surgery during the last 6 months
* Muscle disorders causing leg muscle weakness
* Any disorder causing chronic pain or pain during walking with pain score > 6 on scale from 1-10
* Severe vision problems, causing inability to walk unassisted
* General
o Acute infections affecting general condition
o Recent hospitalization (<4 weeks)

Study design

Design

Study phase:	2
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:	Recruiting
Start date (anticipated):	29-01-2021
Enrollment:	69
Type:	Actual

Ethics review

Approved WMO

Date:	14-10-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	02-12-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-06-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-09-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL70130.091.19