The value of near-infrared spectroscopy and blood pressure measurements in estimating future fall risk in older adults.

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Primary Objective: To investigate which measures/definitions from continuous BP measurements (using Finapres) and from cerebral oxygenation measurements (using NIRS) are associated with associated with future fall incidents in older adults at risk...

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

Summary

ID

NL-OMON56929

Source
ToetsingOnline

Brief title
Predicitive value of NIRS and blood pressure measurements in fall risk.

Condition

- Other condition

Synonym
Falls

Health condition

Valincidenten bij oudere volwassenen.

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Amsterdams universiteitsfonds

Intervention

Keyword: blood pressure, Falls, older adults, orthostatic hypotension

Outcome measures

Primary outcome

The main study parameter is the time to first fall

Secondary outcome

Secondary outcome measures are: number of falls during follow-up, injurious

falls, number of injurious falls, falls history and patient recorded outcomes.

Study description

Background summary

Falls, with or without injury, is a common problem among older adults. Orthostatic hypotension (OH) (low blood pressure when standing), which is common in the older adults, is an important risk factor for falls.
OH is often overlooked with the most commonly used method of measuring OH (intermittent blood pressure measurements using a blood pressure monitor on the upper arm). Previous research has shown that measuring blood pressure via non-invasive continuous blood pressure measurements (Finometer) has added value for finding OH in older fallers. This technique is currently mainly used in specialized clinics (such as the AMC). Another technique that may be of added value in detecting OH-related fall risk is the use of near-infrared spectroscopy (NIRS). This is a sensor that is worn on the forehead and provides a reflection of the cerebral blood flow. This technique is currently only used for research purposes.

At our fall clinic, the two blood pressure measurements methods during postural change is part of usual care. Measuring cerebral blood flow using NIRS will be an addition to this. In addition, we ask participants to keep a fall calendar for 1 year.

Our aim is to investigate which outcomes of continuous blood pressure measurements with Finapres and measurements of cerebral oxygenation with NIRS are associated with (future) fall risk in older adults at risk of an OH-related fall. We will study various cut-off values, definitions, time points and OH-related symptoms to quantitatively estimate the future fall risk and thus take a first step in finding the optimal OH-related variables for fall prediction.

Study objective

Primary Objective:
To investigate which measures/definitions from continuous BP measurements (using Finapres) and from cerebral oxygenation measurements (using NIRS) are associated with associated with future fall incidents in older adults at risk of falls.

Secondary Objective(s):
To investigate which measures/definitions from continuous BP measurements (using Finapres) and from cerebral oxygenation measurements (using NIRS) are associated with secondary fall outcomes, including: number of falls, injurious falls, number of innjurious falls, history of (recurrent) falls.

Study design

Prospective cohort study

Study burden and risks

The risks of participating in this study are negligible. The postural changes that subjects are asked to perform (from lying down to standing) resemble activities from everyday life. Participants may experience dizziness or other symptoms related to standing up. However, the requested postural is part of the usual care of the outpatient fall clinic.
The burden of wearing the NIRS (2 sensors on the forehead) is negligible. Maintaining the fall calendar will take a few minutes per week.

Contacts

Public
Amsterdam UMC

meibergdreef 9
Amsterdam 1105AZ
NL

Scientific
Amsterdam UMC

meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

1.65 years or older
2.History of a fall (in the past year)
3.Ability to perform supine-to-stand manoeuvres.
4.Ability to sign informed consent.
5.a Mini-Mental State Examination score of 21 points or higher or a Montreal Cognitive Assessment - Dutch score of 16 points or higher
6.Sufficient command of the Dutch language

Exclusion criteria

1. Physically not able to perform sit-to-stand and supine-to-stand manoeuvres.
2. Estimated life expectancy of less than one year.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-12-2024
Enrollment:	141
Type:	Actual

Medical products/devices used

Generic name:	PortaLite MKII
Registration:	No

Ethics review

Approved WMO

Date:	31-07-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL85457.018.24