

Improving falls prevention in older persons: the value of a systematic CardioVascular Evaluation - Pilotstudy

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To assess the effectiveness of an additional cardiovascular assessment and intervention to a multidisciplinary falls-intervention.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational non invasive

Summary

ID

NL-OMON37392

Source

ToetsingOnline

Brief title

CAVE-P

Condition

- Cardiac disorders, signs and symptoms NEC
- Decreased and nonspecific blood pressure disorders and shock

Synonym

blood pressure problems, Heart disease

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiovascular evaluation, Falls prevention, Older persons, Syncope

Outcome measures

Primary outcome

Primary outcome parameter will be fall incidents.

Secondary outcome

Secondary outcome measures will be cardiovascular events, adherence to advices, fall-related injuries and quality-adjusted life years.

Study description

Background summary

Falls form a major healthcare problem in our aging society. Current falls guidelines are still hampered by a lack of underlying evidence. Recently, we have shown that cardiovascular abnormalities form a major fall-risk factor in older persons, however, effectiveness of treating these abnormalities is still uncertain. Adding a cardiovascular intervention to the multifactorial falls intervention may reduce falls and subsequent injury.

Study objective

To assess the effectiveness of an additional cardiovascular assessment and intervention to a multidisciplinary falls-intervention.

Study design

In a pilotstudy, all older patients visiting the falls clinic with a positive falls history (N=15) will be eligible. At inclusion all participants will receive regular care. The intervention group will receive an echocardiography and tilt table testing with assessment of orthostatic hypotension, vasovagal collapse and carotid sinus hypersensitivity. This will be followed by a multidisciplinary protocolized treatment advice. Subsequent treatment comprises drug interventions, (para-)medical therapies or invasive treatment. During a 6-month follow-up falls, fall-related injuries, cardiovascular events and quality of life will be assessed.

Study burden and risks

Burden: Performing the cardiovascular assessment will take 2 hours, preferably immediately following the visit to the falls clinic. Participant might experience lightheadedness and/or vasovagal collapse during tilt-table testing. Participants will be asked to fill out a weekly falls calendar during six months that will be sent three-monthly.

Risks: Carotid sinus massage is associated with the occurrence of Transient Ischemic Attacks (TIA) in less than 1 in 10.000 massages.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Positive falls history, as defined by one or more falls in the previous year

Exclusion criteria

Age \geq 64 years

Cognitive dysfunction as defined by a Mini-Mental State Examination of 21 (out of 30) points or lower

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): 16-03-2012

Enrollment: 15

Type: Actual

Ethics review

Approved WMO

Date: 06-03-2012

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	NL39359.018.12