

Examination of the risk and rate of falling and the stride variability in a population of geriatric elderly with and without vertebral fractures.

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The primarily objective of this study is to examine whether elderly with vertebral fractures fall more often in a 6-month period following the first visit at the day clinic of the Geriatrics Department of the Slotervaart Hospital, than elderly...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Observational non invasive

Summary

ID

NL-OMON34287

Source

ToetsingOnline

Brief title

Falls and vertebral fractures in geriatric patients.

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)

Synonym

osteoporosis with spine fractures, vertebral fractures

Research involving

Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis

Source(s) of monetary or material Support: Slotervaartziekenhuis zelf

Intervention

Keyword: elderly, falls, stride variability, vertebral fractures

Outcome measures

Primary outcome

The amount of falls in the 6-month period following the first visit at the day clinic.

Secondary outcome

Risk profile for falling in the future (by questionnaire)

Gait characteristics (by walking tests)

Study description

Background summary

Previously research proved that elderly with vertebral fractures have an impaired balance control according to elderly without vertebral fractures. It can be hypothesized that elderly with vertebral fractures fall more often than elderly without vertebral fractures.

Study objective

The primary objective of this study is to examine whether elderly with vertebral fractures fall more often in a 6-month period following the first visit at the day clinic of the Geriatrics Department of the Slotervaart Hospital, than elderly without vertebral fractures.

At the day of the visit, a walking test will be taken to perform a gait analysis and obtain gait characteristics. There might be a relation between the amount of falls in the 6-month period and the gait characteristics.

There will also be determined a risk profile for falling in the future. This will be done by a questionnaire. This risk profile might also correlate with

the gait characteristics and the amount of falls in the 6-month period.

Study design

This is a prospective cohort study. Patients who visit the day clinic of the Geriatrics Dpt. of the Slotervaart Hospital for the first time, will be asked to participate in this study. Furthermore, patients who have visited the day clinic <6 months ago and come back for a visit, will be asked to participate in this study.

At this day of their first visit, the participants will be asked to do a walking test. There will be done an questionnaire by interview to determine the risk profile for falling in the future.

In the 6-months following that visit, the participants will be asked to record the amount of falls weekly on a fall-and-fracture-calendar.

Study burden and risks

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Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Subjects will be included in this study when they*

- are 70 years or older, and visit the day clinic of the Geriatric Department of the Slotervaart Hospital in Amsterdam for the first time, or have visited the day clinic in the past 6 months and come back for a follow-up visit;
- can walk safely for 3 minutes without any aid (e.g. by walking stick or wheeler);
- understand and speak Dutch or English and have a MMSE score of 18 or higher.

Exclusion criteria

Subjects will be excluded from this study when they*

- have any mobility problems due to (lateral) neurological or orthopedic disorders with function limitations of one or both legs;
- don't understand the instructions of the researcher.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	18-10-2010

Enrollment:	120
Type:	Actual

Ethics review

Approved WMO	
Date:	13-10-2010
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO	
Date:	24-11-2010
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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	NL33825.048.10