

Determinants of falls risk in older orthopaedic patients

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

Summary

ID

NL-OMON37122

Source

ToetsingOnline

Brief title

VALOP study

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym

hip fractures, osteoarthritis (degenerative joint disease), upper extremity symptoms

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar

Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: accidental falls, elderly, gait, orthopedics

Outcome measures

Primary outcome

Number of falls, one year postoperatively (prospective)

A fall is defined as an unintentional change in position resulting in coming to rest at a lower level or on the ground.

Secondary outcome

not applicable

Study description

Background summary

The ageing population faces an increased risk of falling and of the fall consequences. It is estimated that about 33% of the elderly fall each year and falls often result in injuries, disability and inactivity. The strongest risk factors for fall in elderly include previous falls, strength impairments, gait impairments, balance impairments and medication. A specific population in which many of the fall risk factors are present are older orthopaedic patients. Visits of these patients to orthopaedic outpatient departments are often the direct or indirect result of a fall. Insight in fundamental determinants of fall risk in elderly orthopaedic patients is lacking but necessary for developing and implementing specific interventions for this diverse, but highly fall prone population.

Study objective

The overall aim of the present study is to identify the determinants of (recurrent) falls before and after orthopaedic surgery, either due to fall-related injuries or to lower limb joint replacements, in subpopulations of older orthopaedic patients. Primary Objectives:
To study differences in retrospective and prospective fall risk and its associations with (determinants of) strength, balance and gait, 1) between patients that receive surgery to either the lower extremities or the upper extremities because of a fall, 2) between patients with osteoarthritis (OA)

that receive either a total hip arthroplasty (THA) or a total knee arthroplasty (TKA), 3) between patients that receive surgery at the hip either because of OA or because of a fall.

Study design

The study will be a longitudinal observational cohort study with a follow-up of one year.

Study burden and risks

The risks associated with participation in this study are considered to be very low. The burden of participating in this study will be, in addition to care as usual, the filling in of a questionnaire 5 times (at baseline, 3, 6, 9 and 12 months) and registering the number of falls using a weekly diary for 12 months for the whole study population. In addition to the usual assessments at the regular follows-up, also the timed up and go test and a two times 50m walk will be part of the study. A small representative part of the study population will be asked to visit the facilities of the Faculty of Human Movements Sciences at the VU University. These participants will be asked to walk on a treadmill, perform the Physiological Profile Assessment and wear inertial sensors at home for three times one week.

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

- Patients that have to undergo orthopaedic surgery at the hip or upper extremities because of a fall fracture and patients that have to undergo a primary THA or TKA because of OA, at the Medical Centre Alkmaar,
- Age over 65 years.

Exclusion criteria

- Patients with rheumatoid arthritis,
- Patients suffering from insulin dependent diabetes,
- Patients lacking understanding of the Dutch language,
- Patients having cognitive impairments (i.e. Mini Mental State Examination score < 18)
- Patients treated for or diagnosed with neurological or muscle disorders which make assessment of balance and gait not possible,
- Patients using medication that affect balance and gait.
- Patients with sever visual problems that affect balance and gait.
- Patients who suffer from OA with genu varus and valgus deformity of > 10°
- Patients with a history of pathological fractures
- Bedridden patients before orthopaedic surgery

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	24-06-2013
Enrollment:	364
Type:	Actual

Ethics review

Approved WMO	
Date:	19-03-2013
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Not approved	
Date:	29-11-2013
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO	
Date:	31-01-2014
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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

CCMO

ID

NL42395.094.12