Prospective evaluation of bone strength, physical activity, falls, subsequent fractures and mortality in patients presenting with a recent clinical fracture.

Published: 17-12-2013
Last updated: 22-04-2024

The primary objective is to assess bone structure parameters and bone strength by high resolution peripheral quantitative CT evaluation (HRpQCT) and physical activity in relation with subsequent falls, fractures and mortality in patients with a...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone, calcium, magnesium and phosphorus metabolism disorders
Study type	Observational invasive

Summary

ID

NL-OMON41637

Source
ToetsingOnline

Brief title
Bone strength and physical activity in patients with a recent fracture

Condition

- Bone, calcium, magnesium and phosphorus metabolism disorders
- Fractures

Synonym
loss of bone mass

Research involving
Human

Sponsors and support

Primary sponsor: Viecuri Medisch Centrum voor Noord-Limburg
Source(s) of monetary or material Support: Stichting De Wijerhorst

Intervention

Keyword: Bone strength, Falls, Fracture, Osteoporosis

Outcome measures

Primary outcome

Bone structure parameters, bone strength, physical activity, falls, subsequent fractures and mortality.

Secondary outcome

In addition, parameters assessed during regular care will be investigated such as clinical risk factors for fractures and osteoporosis, dietary calcium intake, fall risk assessment, muscle strength and function, gait quality, bone mineral density and laboratory analysis.

Study description

Background summary

The risk for a subsequent fracture is significantly higher in patients presenting with a fracture compared to individuals without a previous fracture and is highest within the first 2 years after the initial fracture. The risk for a subsequent fracture is not dependent of BMD as measured by conventional DXA. In recent studies, it has been shown that HRpQCT measurements provide information about bone structure, bone quality and bone strength in addition to BMD measurements. Diagnostic strategies should be focussed on bone quality and bone strength and fall prediction in the patients at high risk for falls, subsequent fracture and mortality such as patients with a recent fracture. Therefore, we conduct a prospective observational study in 500 patients aged 50 years and older who present with a clinical fracture for evaluation of bone strength, physical activity, falls, subsequent fractures and mortality during a

follow-up period of 3 years.

Study objective

The primary objective is to assess bone structure parameters and bone strength by high resolution peripheral quantitative CT evaluation (HRpQCT) and physical activity in relation with subsequent falls, fractures and mortality in patients with a recent clinical fracture.
Secondary objectives are to study:
* the relation between bone strength assessed by HRpQCT and conventional bone mineral density (BMD) measurement by Dual-energy X-ray Absorptiometry (DXA);
* the relation between falls and subsequent fractures;
* the determinants of mortality;
* the ability of standard muscle strength tests (by handgrip strength, upper leg strength measured by MicroFet, Timed Up & Go test (TUG) and Chair Stand Test) and gait analyses (Six-Minute Walk Test (6MWT)) to predict falls and subsequent fractures;
* the influence of falls and subsequent fractures on quality of life.

Study design

The study is designed as a prospective observational study with a follow-up period of 3 years.

Study burden and risks

According to regular care, patients with a recent clinical fracture are referred by the trauma surgeon for an evaluation at the FLS (previously known as osteoporosis outpatient clinic). At the first visit, clinical risk factors for osteoporosis, fractures and falls are registered and additionally muscle strength and gait tests, bone mineral density measurement (DXA) and laboratory analysis are performed. At the second visit, patients receive the results of the muscle strength and gait tests, bone mineral density measurement (DXA) and laboratory analysis and when needed disorders are further analysed and patients are being treated.
For study purposes bone strength will be measured by HRpQCT, two activity monitors (MOX and ActivPAL3) will be attached to the upper leg for a 7-day analysis of physical activity and an additional blood sample will be collected. These study related procedures will be performed during the second regular care visit at the osteoporosis outpatient clinic. During follow-up, two telephone calls are planned at 3 and 6 months after inclusion for evaluation of quality of life, falls and subsequent fractures. Also three follow-up visits (one, two and three years after baseline visit), will be planned for assessment of bone strength by HRpQCT, muscle strength and function tests, quality of life and evaluation of falls, subsequent fractures and mortality.

Contacts

Public
Viecuri Medisch Centrum voor Noord-Limburg

Tegelseweg 210
Venlo 5912 BL
NL
Scientific
Viecuri Medisch Centrum voor Noord-Limburg

Tegelseweg 210
Venlo 5912 BL
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patients aged 50 years and older with a recent fracture that is being evaluated at the FLS at VieCuri MC.
2. Patients who understand the conditions of the study and are willing and able to comply with the scheduled study procedures
3. Patients who signed the Ethics Committee approved specific Informed Consent Form prior to inclusion.

Exclusion criteria

1. Patients with malignancy metastatic to the bone.
2. Patients with osteomyelitis.

3. Patients with fractures due to failure of a prosthesis.
4. Patients, who as judged by the Principal Investigator, are mentally incompetent. Patients who are compos mentis and understand the patient information, will not be considered mentally incompetent.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-10-2014
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	17-12-2013
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	09-04-2015
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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	NL45707.072.13

Study results

Date completed:	04-06-2019
Actual enrolment:	500