

Suitability of the Dutch osteoporosis case-finding instrument, as a tool for vertebral fracture case-finding in a primary health care setting.

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The aim of this study is to assess the sensitivity, specificity and predictive value of the Dutch osteoporosis case-finding instrument as a tool for vertebral fracture case-finding in a primary health care setting. Furthermore the impact of a...

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

Summary

ID

NL-OMON33583

Source

ToetsingOnline

Brief title

Vertebral fracture case-finding

Condition

- Bone, calcium, magnesium and phosphorus metabolism disorders

Synonym

fractured vertebrae, vertebral fracture

Research involving

Human

Sponsors and support

Primary sponsor: Stichting Synergos

Source(s) of monetary or material Support: Projectgelden DCH

Intervention

Keyword: Case-finding, Depressive symptoms, Quality of life, Vertebral fracture

Outcome measures

Primary outcome

The primary outcome is the existence of a positive indication for bone mineral density measurement according to the Dutch osteoporosis case-finding instrument, the presence of osteoporosis or osteopenia as measured with DXA, and vertebral fractures determined using VFA.

Secondary outcome

The secondary outcomes are:

- *depression* as measured with the Edinburgh Depression Scale (EDS)
- *quality of life*, determined by means of the World Health Organisation Quality of Life brief Questionnaire (WHOQOL- BREF)
- "illness perception" assessed with the Brief Illness Perception Questionnaire (Brief IPQ),

Study description

Background summary

Vertebral fractures (VF) are highly prevalent and are often a manifestation of osteoporosis. They are associated with decreased quality of life and health outcomes and a higher prevalence of depressive symptoms. It is estimated that only one third of all vertebral fractures receive medical attention while vertebral fractures play a major role in the Dutch osteoporosis case-finding instrument. Furthermore, vertebral fractures are strong predictors of future fractures in general which means that identifying patients at risk is

important.

Study objective

The aim of this study is to assess the sensitivity, specificity and predictive value of the Dutch osteoporosis case-finding instrument as a tool for vertebral fracture case-finding in a primary health care setting. Furthermore the impact of a vertebral fracture on the well being will be studied and the illness perception of osteoporosis will be taken into account.

Study design

A cross-sectional study will be performed.

Study burden and risks

All participants included in the study will receive Dual Energy X-ray Absorptiometry (DXA) and VFA, which are both low invasive methods of assessing bone mass density (BMD) and vertebral fractures. All persons are receiving DXA regardless of participation in the studie, so only the VFA is addedd as extra burden for participants. Moreover, participants are asked to fill in a set of questionnaires at home which will take 25 minutes.

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

Females need to be aged 50 or above, males 65 years or more.

Exclusion criteria

Insufficient knowledge of the Dutch language.

Impaired cognitive abilities.

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): 01-01-2010

Enrollment: 400

Type: Actual

Ethics review

Approved WMO

Date: 22-12-2009

Application type: First submission

Review commission: METC Maxima Medisch Centrum (Veldhoven)

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	NL25065.015.08