# Implementation of a strategy of osteoporosis screening in patients over 50 years of age with a first fracture

Submission date Recruitment status [X] Prospectively registered 23/08/2007 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 23/08/2007 Completed [ ] Results Individual participant data Last Edited Condition category Record updated in last year 26/09/2007 Musculoskeletal Diseases

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

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#### Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

#### Scientific Title

#### Study objectives

The nurse practitioner will actively approach all fracture patients above the age of 50 for screening and intensive treatment of osteoporosis. This will improve the number of fracture patients screened and treated for osteoporosis.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics approval received from VU University Medical Center Ethics Board, Amsterdam, on the 21st June 2007 (ref: 2007/132).

#### Study design

Multicentre, parallel group clinical trial

#### Primary study design

Interventional

#### Secondary study design

Non randomised controlled trial

#### Study setting(s)

Hospital

#### Study type(s)

Screening

#### Participant information sheet

#### Health condition(s) or problem(s) studied

Osteoporosis screening

#### **Interventions**

In the implementation group the patients will be screened for osteoporosis by Dual energy X-ray Absorptiometry (DXA) measurement, and a spine X-ray will be performed. At baseline and after 12 months a blood sample will be taken. At baseline, after 3, 6, 9 and 12 months questionnaires will be performed. The follow up period is 1 - 1.5 years (depending on the time it takes to include enough patients). Patients will be treated with anti-osteoporosis medication according to the CBO guidelines (first choice bisphosphonates).

In the parallel group only the questionnaires will be performed.

#### Intervention Type

#### Other

#### **Phase**

**Not Specified** 

#### Primary outcome measure

- 1. Percentage of patients with a fracture of 50 years and older that is screened by a fracture nurse for osteoporosis (the goal is 70%)
- 2. Percentage of patients that are screened and treated and still use their medication after one year (the goal is 70%)

#### Secondary outcome measures

- 1. Percentage of patients that present with a fracture within a year of the initial fracture
- 2. Percentage screened patients and percentage compliant patients in the fracture nurse group compared to the parallel group
- 3. The costs and barriers to implement a fracture nurse

The final follow up will take place after one year, the patients will be contacted every three months.

#### Overall study start date

01/09/2007

#### Completion date

01/12/2009

## **Eligibility**

#### Key inclusion criteria

All patients 50 years of age or older, who have a clinical fracture and a low Bone Mineral Density (BMD) defined as a T score greater than or equal to 2.

#### Participant type(s)

Patient

#### Age group

**Not Specified** 

#### Sex

**Not Specified** 

#### Target number of participants

1650

#### Kev exclusion criteria

- 1. Patients with a fracture after a traffic accident
- 2. Patients with a pathological fracture
- 3. Patients with fractures of hand, foot or scull
- 4. Serious co-morbidity or dementia
- 5. Incapable of visiting the out patient clinic

#### Date of first enrolment

01/09/2007

#### Date of final enrolment

01/12/2009

### Locations

#### Countries of recruitment

Netherlands

# Study participating centre Vrije University Medical Centre

Amsterdam Netherlands 1081 HV

# Sponsor information

#### Organisation

Vrije University Medical Centre (VUMC) (The Netherlands)

#### Sponsor details

Department of Rheumatology Amsterdam Netherlands 1081 BT

#### Sponsor type

Hospital/treatment centre

#### Website

http://www.vumc.nl/english/

#### **ROR**

https://ror.org/00q6h8f30

# Funder(s)

#### Funder type

Research organisation

#### Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

# **Results and Publications**

**Publication and dissemination plan**Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**Not provided at time of registration