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

Submission date
23/08/2007

Recruitment status
No longer recruiting

Registration date
23/08/2007

Overall study status
Completed

Last Edited
26/09/2007

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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

N/A

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

Key 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