Implementation of a strategy of osteoporosis screening in patients over 50 years of age with a first fracture, with intensive treatment and follow-up by a nurse-practitioner to prevent recurrent fractures in those patients with diagnosed osteoporosis

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Is it possible to improve routine detection and treatment of osteoporosis after an initial fracture?I) is it possible to increase the proportion of patients adequately screened and categorized as to the presence of osteoporosis from current practice...

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

Summary

ID

NL-OMON31623

Source
ToetsingOnline

Brief title
Implementation of osteoporosis screening

Condition

- Fractures

Synonym
compliance and medication adherence, osteoporosis and decreased bone mineral density

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonNW

Intervention

Keyword: fracture nurse, implementation, osteoporosis, screening

Outcome measures

Primary outcome

I) is it possible to increase the proportion of patients adequately screened

and categorized as to the presence of osteoporosis from current practice of

5-40% to at least 70%?

II) in patients found to have osteoporosis, is it possible to:

a) start treatment in nearly all applicable patients?

b) maintain the proportion of patients still on anti-osteoporotic treatment

after 1 year at 70% of those starting treatment?

Secondary outcome

III) are the data on subsequent fracture rates compatible with a reduction to

4%?

IV) is the proportion of patients screened for osteoporosis with a DXA

measurement significantly higher in the implementation group (with fracture

nurse) than in the control group (without a fracture nurse; 'usual care')?

V) is the proportion of patients still on anti-osteoporotic treatment after 1

year significantly higher in the implementation group than in the control group?

VI) what are the costs associated with the implementation of an osteoporosis

nurse and how do these costs compare to the health benefits obtained.

VII) what are the practical barriers encountered in trying to achieve the above mentioned goals?

VIII) what are the practical barriers in the implementation of an osteoporosis nurse, and how can these be overcome?

concerning population 2 and 3:

1. a) what proportion of patients without vertebral fractures and with a T score of * -1 and >-2, has sustained a new clinical fracture one year after the initial fracture?

b) what proportion of patients already being treated with anti-osteoporotic medication, has sustained a new clinical fracture one year after the initial fracture?

2. is the proportion of patients still on anti-osteoporotic treatment after 1 year significantly different in the implementation group than in the group of patients who are being treated by another clinician or general practitioner?

Study description

Background summary

The aging population frequently incurs osteoporotic fractures that are associated with high morbidity and increased mortality. Patients presenting with their first fracture are at high risk for reccurence. Patients aged 50 years or older are often diagnosed with osteoporosis after a DXA measurement. Effectieve and well tolerated drugs can reduce the incidence of new fractures roughly by half. In current practive, only a small percentage of patients presenting with a fracture above the age of 50 years are screened, and if needed treated, for osteoporosis.

In a few hospitals in the Netherlands a nurse practitioner is appointed as a central person, to screen and if needed treat, patients with fractures above the age of 50.

Study objective

Is it possible to improve routine detection and treatment of osteoporosis after an initial fracture?
I) is it possible to increase the proportion of patients adequately screened and categorized as to the presence of osteoporosis from current practice of 5-40% to at least 70%?
II) in patients found to have osteoporosis, is it possible to:
a) start treatment in nearly all applicable patients?
b) maintain the proportion of patients still on anti osteoporotis treatment after 1 year at 70% of those starting treatment?

Study design

4 hospitals participating in the implementationgroup: a nurse practioner actively contacts patients above the age of 50 with a clinical fracture to offer them screening (through DXA and risk factor analysis) and treatment of osteoporosis. If the patient is diagnosed with osteoporosis, treatment will be started, as well as advice on lifestyle and suppletion of vitamine D and calcium. Every three months the patients will be contacted (through a telephone call or a visit to the outpatient clinic) to assess, among other things, compliance and new fractures.

4 hospitals participating in the control group: in these centers there is no nurse pratitioner, but the usual care following a fracture. The patients will receive information at home about the study and will be asked to participate. Every three months they will receive questionairs.

Study burden and risks

In the control group there is no additional burden or risk; patients will receive the usual care following a fracture.
In the implementation group most of the clinical investigations are normal patient care (DXA measurement, blood samples) and offer no additional burden or risk. A second DXA measurement after 12 months is optional and not considered normal patient care, but its risk/burden is minimal. (comparable to an X ray)

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

population 1:
-All patients 50 years of age or older, who have a clinical fracture and a low BMD defined as a T score * 2
population 2:
-All patients 50 years of age or older, who have a clinical fracture and a BMD defined as a T score of * -1 and >-2
population 3:
-All patients of 50 years or older, who have a clinical fracture and ar already being treated with anti-osteoporotic medication

Exclusion criteria

-patients with a fracture after a traffic accident
-patients with a pathological fracture
-patients with fractures of hand, foot or scull

-serious comorbidity or dementia
-incapable of visiting the out patient clinic

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2007
Enrollment:	1650
Type:	Actual

Ethics review

Approved WMO

Date:	18-07-2007
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL18087.029.07