New (vertebral) fracture incidence in a patient population with a previuos fracture

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Amount of new fractures in this study population, divided in 4 different groups:group 1 MVF (+) osteoporosis (+)group 2 MVF (+) osteoporosis (-)group 3 MVF (-) osteoporosis (+)group 4 MVF (-) osteoporosis (-) (control group/less risk factors)The…

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

Summary

ID

NL-OMON32423

Source
ToetsingOnline

Brief title
Incidence of new fractures in high risk population

Condition

- Fractures

Synonym
fracture and broken bone, osteoporosis and decreased bone mineral density, risk factors

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Nycomed

Intervention

Keyword: (vertebral) fractures, follow up, osteoporosis, risk factors

Outcome measures

Primary outcome

Incidence of new fractures in this study population.

Secondary outcome

Analyzing the changes of bone mineral density in this population after

treatment or no-treatment and the effect of therapy in patients taking

medication and compliance.

Study description

Background summary

Therapy of osteoporosis is started in patients who meet the criteria of the guideline for treatment of osteoporosis set up by CBO for instance patients with a bone mineral density (BMD) < - 2,5. But unfortunately a lot of people with osteopenia (BMD between -1 and -2,5) fracture. Recent research data show 50% of all patients with a non vertebral fracture have a morfometric vertebral fracture (MVF). A morfometric vertebral fracture is a risk factor for future fractures in despite of the BMD concluded those authors (Dumitrescu et al). Systemic follow up of these patients will show new fractures, vertebral and non vertebral.

Study objective

Amount of new fractures in this study population, divided in 4 different groups:
group 1 MVF (+) osteoporosis (+)
group 2 MVF (+) osteoporosis (-)
group 3 MVF (-) osteoporosis (+)
group 4 MVF (-) osteoporosis (-) (control group/less risk factors)
The secundair aim of this study is to measure the BMD difference and to look at the therapeutic effects and therapeutic compliance.

Study design

prospective, observational (cohort) study

Study burden and risks

The participants burden is minimalized to one visit to the reumatologist and previous a DXA scan, X-ray (not all patients), a blood sample and a questionnaire. This all is considerd to be normal patient care and minimal burden and risk to the patient.

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

women above 50 years

women were included in previous research (Dumitrescu)

Exclusion criteria

male
patients with dementia
patients living abroad
patients with a life expectancy <6 months
patients who are deceased

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-07-2008
Enrollment:	492
Type:	Actual

Ethics review

Approved WMO

Date:	18-06-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL21506.068.08