Stepped screening of fracture risk. A case finding and treatment program for women of 65 years of age and older in primary care.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23553

Source
Nationaal Trial Register

Brief title
SOS = Salt Osteoporosis Study

Health condition

Osteoporosis; Fracture Risk; Bone Sparing Drugs; Bisfosfonates; Postmenopausal Osteoporosis; Osteoporose Fractuurpreventie; Fracturen; Botsparende medicatie; Bisfosfonaten

Sponsors and support

Primary sponsor: VUmc Amsterdam
SALT Koog aan de Zaan
Stichting ArtsenLaboratorium en Trombosedienst
Molenwerf 11
1541 WR Koog aan de Zaan
075 6156251
www.salt.nl
info@salt.nl
Source(s) of monetary or material Support: Stichting Achmea Gezondheidszorg

VUmc Amsterdam
SALT Koog aan de Zaan

Intervention

Outcome measures

Primary outcome

Time to new fracture and number of fractures after 36 months in patients with high fracture risk according to FRAX assessment.

Secondary outcome

1. Time to new fracture;

2. Number of fractures after 36 months;

3. Medical cost;

4. Death rate;

5. Falls.

Study description

Background summary

In recent years, several medications have become available for the treatment of osteoporosis. These medications have been shown to be effective in reducing fractures with 20-50% in selected populations. However the effectiveness of these treatment regimes has not yet been examined in a general primary care population.

The objective of the study is to examine whether the structured identification and subsequent treatment of patients with a high fracture risk in primary care reduces fractures in comparison to usual care. We hypothesize that this primary care case finding and treatment program reduces the incidence of fractures in primary care patients having a high risk of fractures.

We will invite women of 65 years of age or older to participate in the study. Patients with risk factors for osteoporosis who are randomised in the treatment group will undergo a case

finding and treatment program at the start of the trial whereas the treatment program in the control group will be delayed for 3 years.

All women aged 65 years or over receive an invitation to participate via their GP and are sent a questionnaire regarding risk factors for osteoporose. Main exclusion criteria are: Actual use of bisphosphonates, unable to participate in the trial according to the GP, previous bisphosphonates use for two years or more in the last 5 years, use of high dosage of corticosteroids, weight 135 kg or more. Women with at least one serious risk factor for osteoporosis (previous fracture after 50 years of age, parents or siblings with hip fracture, low body weight, reduced mobility will be included in the trial and randomised individually on a 1:1 basis to the control group and the intervention group.

The women with clinical risk factors for osteoporosis who are randomised in the intervention group will receive bone densitometry and instant vertebral assessment using DXA and blood tests to exclude secondary osteoporosis. Subjects with an increased fracture risk according to the FRAX tool using cut off points that have been assessed based on the bone densitometry results in the Longitudinal Aging Study of Amsterdam will be offered a treatment program.

The women in the control group will be offered the treatment program only after 3 years. Those with an indication for bone densitometry according to the current Dutch guideline will be notified and are free to consult their GP for additional examinations and treatment. All subjects with risk factors for osteoporosis in the control group will undergo the same examinations as the intervention group at the end of the trial and will be classified in low and high fracture risk according to these measurements.

All subjects with a least one risk factor for osteoporosis and 10% of the subjects without risk factors will receive questionnaires after 1,5; 3 and 4,5 years. Notified fractures will be verified with the GP or the hospital. Primary outcome is time to first new fracture during the first 3 years of the trial.

Inclusion will continue until n=12500 women have been enrolled into the program or 1700 women in the intervention group have been identified with high fracture risk.

Study objective

Stepped cased finding of women with increased fracture risk using questionnaires , bone densitometry and vertebral morfometry and treatment with bone sparing drugs of those with

indcreased fracture risk in primary care reduces fractures.

Study design

0,18, 36 and 54 months.

Intervention

Women with at least one serious risk factor for osteoporosis (previous fracture after 50 years of age, parents or siblings with hip fracture, low body weight, reduced mobility will be included in the trial and randomised individually on a 1:1 basis to the control group and the intervention group.

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Contacts

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Eligibility criteria

Inclusion criteria

1. Female sex;

2. Age 65 years or older;

3. Willing to participate in the study.

Exclusion criteria

1. Actual use of bisfosfonates, strontium ranelate, raloxifene or teriparatide or use during the previous two years;

2. Actual daily use of corticosteroids of 7.5 mg prednisolonequivalent or more;

3. Terminal illness;

4. Unable to participate according to general practitioner;

5. Body weight is 135 kg or more.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2010
Enrollment:	12500
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-07-2010
Application type:	First submission

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
NTR-new	NL2324
NTR-old	NTR2430
Other	METc VUmc : WC2006-98 / WC2008-029
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
Gezondheidsraad. Wet bevolkingsonderzoek: getrapte screening op fractuurrisico.
Den Haag: Gezondheidsraad, 2009; publicatienr. 2009/05WBO.