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A pragmatic randomised controlled trial of the effectiveness and cost-effectiveness of screening for osteoporosis in older women for the prevention of fractures

Submission date
14/05/2007

Recruitment status
No longer recruiting

Registration date
19/06/2007

Overall study status
Completed

Last Edited
15/02/2018

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Osteoporosis is a condition that weakens the bones, making them fragile and more likely to break (fracture). Osteoporotic fractures – in particular hip fractures – have major adverse effects on quality of life in terms of pain and disability. Around 50% of hip fracture patients lose the ability to live independently and 20% die within a year of their fracture. The aim of this study is to investigate whether a community-based screening programme for osteoporosis reduces the incidence of fractures, and is cost effective, in older women (aged 70 - 85 years).

Who can participate?
Women aged 70 to 85 who are not currently on prescription medication to prevent osteoporotic fractures.

What does the study involve?
Participants are randomly allocated to either the screening group or the control group. Those in the screening group have their risk of fracture calculated using data from a questionnaire and, for some participants, results from a DXA (x-ray) scan. Participants above an age-dependent threshold are recommended for treatment (typically bisphosphonate tablets), and to continue treatment for the duration of the study. The risk of fracture is not calculated for participants in the control group, who receive usual care. Participants are followed-up 6 months later and then annually by postal questionnaires and checking of medical records. The proportion of participants sustaining fractures is measured for each group, along with hip fracture rate. Cost-effectiveness is also assessed, as well as the acceptability of the DXA scanning and risk assessment process.

What are the possible benefits and risks of participating?
Participants in the screening group have the opportunity to discuss treatment with their GP that would reduce their fracture risk. In addition, everyone taking part in the study will be helping to determine whether screening would be beneficial in older women. Taking part in this study will

involve some time to complete questionnaires. If a participant in the screening group is invited to have a DXA bone density scan this would involve a single appointment lasting about 15 to 30 minutes with the DXA provider (usually at an NHS hospital trust). The DXA scanner uses much less radiation than a normal x-ray, such as a chest x-ray, and is equivalent to a few days of natural background radiation.

Where is the study run from?
University of East Anglia (UK)

When is the study starting and how long is it expected to run for?
February 2007 to December 2015

Who is funding the study?
1. Medical Research Council (MRC) (UK)
2. Arthritis Research Campaign (UK)

Who is the main contact?
Prof. Lee Shepstone
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Study website
http://www.scoopstudy.ac.uk/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MRC ref: G0601019

Study information

Scientific Title
A pragmatic randomised controlled trial of the effectiveness and cost-effectiveness of Screening for Osteoporosis in Older women for the Prevention of fractures (SCOOP)

Acronym
SCOOP

Study objectives
To investigate whether a community-based screening programme for osteoporosis reduces the incidence of fractures, and is cost effective, in older women (aged 70 - 85 years).

Ethics approval required
Old ethics approval format

Ethics approval(s)
The North West Research Ethics Committee, 20/09/2007

Study design
Two-group pragmatic randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Musculoskeletal Diseases: Osteoporosis

Interventions
Intervention subjects will have a 10-year absolute risk of fracture calculated from a World Health Organization (WHO) risk algorithm based on data from a screening questionnaire and, for some subjects, results from a Dual energy X-ray Absorptiometry (DXA) scan. GPs will be advised of those at high risk and whether to consider treatment.

The control group will have usual care.

Both intervention and control groups will be provided with lifestyle advice through an Arthritis Research Campaign (ARC) booklet on osteoporosis.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
All osteoporosis-related fractures (excluding those of hands, feet, nose and skull), assessed at the annual follow-up visits for 5 years post randomisation.

Secondary outcome measures
1. All clinical fractures (including hip fractures)
2. Quality of life, assessed by the European Quality of life (EQ-5D) and Short Form 12 (SF-12) questionnaires at baseline (immediately prior to randomisation), 6 and 12 months and then annually for 5 years post randomisation
3. Psychological anxiety, assessed by the State-Trait Anxiety Index at baseline, 6 and 12 months and then annually for 5 years post randomisation
4. Mortality (assessed annually for 5 years post randomisation)

A process measure will be treatment adherence as ascertained by an ad-hoc questionnaire at follow-up visits.

Overall study start date
01/02/2007

Completion date
30/12/2015

Eligibility

Key inclusion criteria
1. Female
2. Aged 70 to 85 years
3. Able to provide informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Female

Target number of participants
11,580

Key exclusion criteria
1. Currently known to be on treatment for osteoporosis (other than calcium and vitamin D)
2. Any known co-morbidity that would make entry to the trial inadvisable, in GP's opinion

Date of first enrolment
01/02/2007

Date of final enrolment
01/07/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of East Anglia
Norwich
United Kingdom
NR4 7TJ

Study participating centre
University of Birmingham
United Kingdom
B15 2TH

Study participating centre
University of Bristol
United Kingdom
BS2 8DZ

Study participating centre
University of Manchester
United Kingdom
M13 9PT

Study participating centre

University of Sheffield
United Kingdom
S57 7AU

Study participating centre
University of Southampton
United Kingdom
SO16 6YD

Study participating centre
University of York
United Kingdom
YO10 5DD

Sponsor information

Organisation
University of East Anglia (UK)

Sponsor details
Research Enterprise & Engagement
University of East Anglia
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Sponsor type
University/education

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Government

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Arthritis Research Campaign (UK)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date.

Intention to publish date

Individual participant data (IPD) sharing plan
The trialists plan to make data available on request, subject to terms of data sharing agreement drawn up by University of East Anglia.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/10/2012		Yes	No
Results article	results	24/02/2018		Yes	No