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A randomised trial of a community pharmacist-initiated screening and intervention program for osteoporosis: the OsteoPharm Study

Submission date
04/11/2005

Recruitment status
No longer recruiting

Registration date
26/01/2006

Overall study status
Completed

Last Edited
05/11/2008

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.epicore.ualberta.ca/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
186

Study information

Scientific Title

Acronym
OsteoPharm

Study objectives
A community pharmacist-initiated multifaceted intervention will help increase the diagnosis and treatment of osteoporosis in patients at a high risk for fracture.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the University of Alberta, Health Research Ethics Board-A on the 14th June 2005.

Study design
Randomised, controlled multi-site trial with blinded ascertainment of outcomes

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Osteoporosis

Interventions
Intervention group:
Multifaceted interventions that consist of the following:
1. Screening by community pharmacists

2. Educational session on osteoporosis
3. Quantitative ultrasound (QUS) measurements
4. Referral to the primary care physician

Control group:
Usual care, defined as provision of generic pamphlet on osteoporosis.

Please note that as of 15/01/2008 the anticipated end date of this trial was extended to 30/09/2007. The previous end date of this trial was 01/10/2006.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Composite endpoint of the performance of a bone mineral density test or a new prescription for an osteoporosis medication within four months of study entry.

Secondary outcome measures
1. Each component of the primary outcome
2. Use of calcium and vitamin D supplements
3. Patients osteoporosis related knowledge using the Facts on Osteoporosis Quiz, (FoOQ)
4. Changes in generic health status (RAND-12)
5. Osteoporosis specific quality of life

Overall study start date
16/11/2005

Completion date
30/09/2007

Eligibility

Key inclusion criteria
Males or females who are:
1. Over the age of 50
2. Considered to be at a high risk for osteoporosis and fractures as defined by the Osteoporosis Society of Canada Clinical Practice guidelines and as defined specifically for the purposes of this study, i.e., are over the age of 65 years or between 50 - 64 years of age with any one of the following:
2.1. Family history of osteoporosis
2.2. Previous fragility fracture
2.3. Systemic steroids
2.4. Early menopause (for women)
3. Live in the Capital Health Region (Edmonton Region)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
250

Key exclusion criteria
1. Are unable or unwilling to provide informed consent
2. Are on current prescription treatment for osteoporosis
3. Have had a dual energy x-ray absortiometry (DEXA) scan performed in the past two years
4. Are non-English speaking

Date of first enrolment
16/11/2005

Date of final enrolment
30/09/2007

Locations

Countries of recruitment
Canada

Study participating centre
Faculty of Pharmacy and Pharmaceutical Sciences
Edmonton
Canada
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Sponsor information

Organisation
University of Alberta (Canada)

Sponsor details
Faculty of Pharmacy and Pharmaceutical Sciences
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Sponsor type
University/education

Website
http://www.pharmacy.ualberta.ca/

ROR
https://ror.org/0160cpw27

Funder(s)

Funder type
Charity

Funder Name
Institute of Health Economics (IHE) (Canada) (account number: 186)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/03/2006		Yes	No