

Strategies Targeting Osteoporosis to Prevent recurrent Fractures

Submission date 27/08/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 09/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/10/2008	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00152321

Secondary identifying numbers
CIHR-MOP #62906

Study information

Scientific Title

Acronym

STOP-Fracture Study

Study objectives

An evidence-based quality improvement intervention will overcome multiple barriers to best practice and improve rates of diagnosis and effective treatment for osteoporosis in high-risk patients. The intervention will be directed at patients (education and counseling) and their primary care physicians (reminders and opinion leader generated and endorsed single page guidelines).

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Alberta Health Research Ethics Board, first approved 1st December 2003, updated annually on anniversary date, most recent 1st December 2006 (ref: HREB#4478).

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Fragility fracture patients with osteoporosis

Interventions

Multifaceted intervention that consists of the following: patient specific reminders; single page treatment guidelines generated and endorsed by local opinion leaders; patient education and counseling.

Control group is 'usual care', defined as provision of generic osteoporosis-related educational leaflets at time of fracture.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The proportion of patients starting bisphosphonate treatment within 6 months of fracture

Secondary outcome measures

1. Starting any effective osteoporosis treatment (bisphosphonates, calcitonin, raloxifene, or hormone therapy)
2. Bone mineral density testing
3. Self reported diagnosis of osteoporosis and other knowledge
4. Satisfaction with care
5. Health related quality of life

Overall study start date

01/09/2003

Completion date

30/05/2006

Eligibility

Key inclusion criteria

All patients 50 years of age or older, either sex, with a wrist fracture who present to the Emergency Departments or Fracture Clinics at our two study sites will be eligible for study enrollment.

Specifically:

1. Age 50 years or greater
2. Any distal forearm fracture

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

220

Key exclusion criteria

1. Unable to give simple informed consent
2. Unwilling to participate in the study
3. Unable to understand, read, or converse in English
4. Place of residence outside Capital Health
5. Already receiving osteoporosis treatment with a bisphosphonate

- 6. Previously documented allergy or intolerance to a bisphosphonate
- 7. Currently enrolled in the pilot study or other osteoporosis study

Date of first enrolment

01/09/2003

Date of final enrolment

30/05/2006

Locations

Countries of recruitment

Canada

Study participating centre

2E3.07 WMC

Edmonton, Alberta

Canada

T6G 2B7

Sponsor information

Organisation

University of Alberta, Research Services Office (Canada)

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/0160cpw27>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MOP-62906)

Funder Name

Alberta Heritage Foundation for Medical Research (AHFMR) (Canada) - in the form of salary support for investigator(s)

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?
Results article	results	26/02/2008		Yes	No