# Strategies Targeting Osteoporosis to Prevent recurrent Fractures

Submission date Recruitment status Prospectively registered 27/08/2005 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 09/09/2005 Completed [X] Results [ ] Individual participant data **Last Edited** Condition category 28/10/2008 Musculoskeletal Diseases

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

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# Additional identifiers

ClinicalTrials.gov (NCT)

NCT00152321

Protocol serial number

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 quidelines).

## 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

## Study type(s)

Prevention

# 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(s)

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

### Key secondary outcome(s))

- 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

### 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** 

# Healthy volunteers allowed

No

### Age group

Senior

#### Sex

All

### 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)

#### **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**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results articleresults26/02/2008YesNo