# Improving outcome for patients after osteoporotic femoral fracture

Submission date	Recruitment status	[X] Prospectively registered
07/06/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
11/07/2006	Completed	Results
Last Edited	Condition category	Individual participant data
06/06/2016	Musculoskeletal Diseases	Record updated in last year

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

**Prof Hamish Simpson** 

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers
OFF PROTOCOL/01

# Study information

#### Scientific Title

Improving outcome for patients after osteoporotic femoral fracture

#### Acronym

Off Study

#### **Study objectives**

It is possible to accelerate the healing of trochanteric and distal femoral fractures with the systemic administration of therapeutic agents and by doing so pain and functional impairment will be reduced.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Two-centre open-label three-arm randomised assessor-blinded clinical trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

## Study setting(s)

Other

#### Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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

Osteoporosis

#### **Interventions**

Patients will be randomised to one of three groups:

Group one will receive weekly alendronate plus vitamin D and calcium.

Group two will receive daily teriparatide plus vitamin D and calcium.

Group three will receive vitamin D and calcium only.

The treatment period will be six weeks.

#### Intervention Type

#### Supplement

#### Phase

**Not Specified** 

#### Drug/device/biological/vaccine name(s)

Alendronate, teriparatide, vitamin D and calcium

#### Primary outcome measure

The difference between the baseline Johanson Hip Rating Questionnaire (HRQ) score and the HRQ score at six weeks. A target difference of seven to ten points will be considered significant.

#### Secondary outcome measures

Pain and function.

#### Overall study start date

01/09/2006

#### Completion date

01/09/2009

# Eligibility

#### Key inclusion criteria

Patients with acute, traumatic trochanteric or supracondylar femoral fractures who are 55 or older presenting with fragility fractures.

#### Participant type(s)

Patient

#### Age group

Senior

#### Sex

Both

#### Target number of participants

450

#### Key exclusion criteria

- 1. Patients with open fractures, pathological fractures, who have a 'floating knee', associated patellar fracture or simultaneous bilateral fracture.
- 2. Patients with known metabolic bone disease, rheumatoid arthritis and patients with chronic renal failure.
- 3. Patients on steroids, strontium, bisphosphonates and parathyroid hormone.
- 4. Patients with dementia.

#### Date of first enrolment

01/09/2006

#### Date of final enrolment

01/09/2009

#### Locations

#### Countries of recruitment

Scotland

**United Kingdom** 

# Study participating centre Chancellor's Building

Edinburgh United Kingdom EH16 4SB

# Sponsor information

#### Organisation

University of Edinburgh (UK)

#### Sponsor details

QMRI Little France Edinburgh Scotland United Kingdom EH16 4TJ +44 (0)131 242 6200 marise.brown@ed.ac.uk

#### Sponsor type

University/education

#### Website

http://www.ed.ac.uk

#### **ROR**

https://ror.org/01nrxwf90

# Funder(s)

#### Funder type

#### Charity

#### **Funder Name**

**British Orthopaedic Association** 

#### Alternative Name(s)

, BOA

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

Associations and societies (private and public)

#### Location

United Kingdom

# **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