

Improving outcome for patients after osteoporotic femoral fracture

Submission date 07/06/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 11/07/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 06/06/2016	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Pain and function.

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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

United Kingdom

Scotland

Study participating centre

Chancellor's Building

Edinburgh

United Kingdom

EH16 4SB

Sponsor information

Organisation

University of Edinburgh (UK)

ROR

<https://ror.org/01nrxf90>

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration