ISRCTN33363553 https://doi.org/10.1186/ISRCTN33363553

Improving outcome for patients after osteoporotic femoral fracture

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

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

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
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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