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The Warwick Hip Trauma Study

Submission date 23/04/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/04/2010	**Overall study status** Completed	
Last Edited 09/02/2011	**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
7762; Protocol Version 5

Study information

Scientific Title

The Warwick Hip Trauma Study: a randomised clinical trial comparing interventions to improve outcomes in internally fixed intracapsular fractures of the proximal femur

Acronym
WHiT

Study objectives
Controversy exists regarding the optimal treatment for patients with displaced intracapsular femoral neck fractures. The recognised treatment alternatives are arthroplasty and internal fixation. The principal criticism of internal fixation is the high rate of non-union; up to 30% of patients will have a failure of the fixation leading to revision surgery. We believe that improved fracture healing may lead to a decreased rate of failure of fixation. We therefore propose to investigate strategies to both accelerate fracture healing and improve fixation that may significantly improve outcomes after internal fixation of intracapsular femoral fractures. We will test the clinical effectiveness of the osteoinductive agent platelet rich plasma and conduct a pilot study of a novel fixed-angle fixation system.

1. That internal fixation with parallel cannulated screws and intra-fracture injection of platelet-rich plasma (PRP) compared with internal fixation alone leads to a reduced incidence of failure of fixation
2. Additionally to explore the size of the effect on the incidence of fixation failure of a fixed-angle system compared with internal fixation with parallel cannulated screws

Ethics approval required
Old ethics approval format

Ethics approval(s)
Coventry Research Ethics Committee approved on the 6th of July 2009 (ref: 09/H1210/22)

Study design
Randomised standard-of-care controlled blinded pragmatic clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Musculoskeletal; Subtopic: Musculoskeletal (all Subtopics); Disease: Osteoporotic and fragility fractures

Interventions
All participants will have a closed reduction of their fracture. The lower limb will be supported on a fracture table. Internal fixation of the fracture will be achieved through a standard lateral approach with perioperative antibiotic cover in accordance with hospital protocol. Post-operative care will include early active mobilisation managed by a standard physiotherapy rehabilitation regime.
All participants will have routine prophylaxis against deep vein thrombosis. Participants will be randomised to one of three groups:
1. Fixed-angle screw and plate fixation
2. Standard of care fixation and placebo injection
3. Standard of care fixation and PRP injection

Group 1: Fixed-angle screw and plate fixation
Fixation will be with the Targon FN Head Preserving System as described in the manufacturer's operative technique manual.

Group 2: Standard of care fixation
Fixation will be with three parallel cannulated screws. The exact configuration will be left to the discretion of the operating surgeon to ensure the results can be easily generalised. Fixation will be achieved using the standard operative technique.

Group 3: Standard of care fixation and PRP injection
Fixation will be with three parallel cannulated screws. The exact configuration will be left to the discretion of the operating surgeon to ensure the results can be easily generalised. Each screw will be advanced up to but not beyond the fracture such that no compression is achieved before the test substance is injected. The guidewire of one screw will then be removed and 5ml of PRP will be injected down the cannulated screw directly into the fracture site under image intensifier guidance. The guidewire will be immediately replaced and the screw/s will then be advanced to compress the fracture site.

Follow up length: 12 months
Study entry: Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The proportion of participants undergoing re-operation for failure of fixation within one year of sustaining the fracture.

Secondary outcome measures
1. Radiographic non-union rate at 12 months. Non-union will be defined as "failure of the fracture to show signs of bony union on the anteroposterior or lateral radiograph 1 year after surgery".
2. Radiographic evidence of failure of fixation at 6, 12 and 52 weeks
3. Radiographic evidence of avascular necrosis at one year
4. Magnetic resonance imaging at 6, 12 and 52 weeks. This measure will only be recorded for

those participants with capacity to consent.
5. The EQ-5D score at 6, 12 and 52 weeks
6. Length of index hospital stay

Overall study start date
01/08/2009

Completion date
01/08/2011

Eligibility

Key inclusion criteria
1. All patients who present with intracapsular fractures of the proximal femur
2. Male and female, lower age limit of 65 years
3. With or without capacity to consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 225; UK Sample Size: 225

Key exclusion criteria
1. All patients who present late following their injury i.e. more than 48 hours after the index fracture
2. Patients with other serious injuries to either lower limb that would interfere with rehabilitation of the index fracture
3. Patients who are managed non-operatively
4. Patients younger than 65 years

Date of first enrolment
01/08/2009

Date of final enrolment
01/08/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Warwick Medical School
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation
University of Warwick (UK)

Sponsor details
c/o Peter Hedges
Research Support Services
Kirby Corner Road
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Sponsor type
University/education

Website
http://www2.warwick.ac.uk

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Charity

Funder Name
Furlong Research Charitable Foundation (UK)

Funder Name
Bupa Foundation (UK) (ref: TBF-M09-026)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/08/2010		Yes	No