

The Warwick Hip Trauma Study

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Registration date 23/04/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/02/2011	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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**

United Kingdom

England

Study participating centre

Warwick Medical School

Coventry

United Kingdom

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Sponsor information**Organisation**

University of Warwick (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

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