

# Warwick Hip Trauma Evaluation Two

<b>Submission date</b> 09/04/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 09/05/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/10/2018	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Controversy exists regarding the best treatment for independent patients with displaced intracapsular fractures of the proximal femur. The recognised alternatives are hemiarthroplasty being used in many centres. The advantages of total hip arthroplasty (THA) are a functional benefit over hemiarthroplasty and a reduced risk of revision surgery. The principle criticism is the increased risk of dislocation. We believe that an alternative acetabular component may reduce the risk of dislocation but still provide the functional benefit of total hip arthroplasty in these patients. We therefore propose to investigate the dislocation risk of an alternative acetabular component compared with standard components in total hip arthroplasty for independent patients with displaced intracapsular fractures of the proximal femur. The aim of the study is to draw conclusions on observed differences in the dislocation risk between the study groups at one year post-injury.

### Who can participate?

Any patient with an AO/OTA type B3 fracture of the proximal femur.

### What does the study involve?

Eligible patients will be randomly allocated to one of two groups: standard THA or the treatment under investigation (dual mobility THA). After the procedure, all patients will be asked to complete outcome questionnaires at 1 month, 4 months and 1 year post injury. These questionnaires will be completed either by telephone or post.

### What are the possible benefits and risks of participating?

Both treatments require surgery which carries some risks, but these risks are the same and equal to individuals who do not take part. The risks of surgery include the risks of bleeding, risk of deep vein thrombosis, risk of damage to nerves and blood vessels in the surgical area and the risk associated with the anaesthesia.

### Where is the study run from?

The study takes place at University Hospitals Coventry and Warwickshire (UK).

### When is the study starting and how long is it expected to run for?

The study is expected to start in May 2013 with recruitment expected to end in May 2014.

Who is funding the study?  
Orthodynamics (UK)

Who is the main contact?  
Catherine Richmond, Clinical Trial Coordinator  
C.A.Richmond@warwick.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Miss Catherine Richmond

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## Additional identifiers

**Protocol serial number**  
Version 3/ 16th January 2013

## Study information

**Scientific Title**  
A randomised controlled trial comparing total hip replacement with and without the dual mobility cup in the treatment of displaced intracapsular fractures of the proximal femur.

**Acronym**  
WHiTE Two

**Study objectives**  
The aim of this trial is to investigate the dislocation risk of a dual mobility acetabular component compared with a standard component in total hip arthroplasty for independent patients with displaced intracapsular fractures of the proximal femur.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Not provided at time of registration

**Study design**

Single centre multi-surgeon parallel two arm standard of care controlled randomised pilot study embedded

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Proximal Femur Fractures

**Interventions**

Standard total hip arthroplasty or the alternative treatment a total hip arthroplasty with an acetabular component with dual mobility bearing surfaces.

**Intervention Type**

Procedure/Surgery

**Phase**

Not Applicable

**Primary outcome(s)**

Dislocation risk between the trial treatment groups at one year post injury.

**Key secondary outcome(s)**

1. EQ-5D measured at baseline, 4 weeks, 4 months and 12 months
2. ICEpop CAPability measure for Older people (ICE-CAP-O) measured at baseline, 4 weeks, 4 months and 12 months
3. Oxford Hip Score (OHS) measured at baseline, 4 weeks, 4 months and 12 months
4. Mortality
5. Re-operation and cause
6. Length of index hospital stay
7. Complications measured at baseline, 4 weeks, 4 months and 12 months

**Completion date**

01/05/2014

**Eligibility****Key inclusion criteria**

All patients, males and females, over 60 years of age with a AO/OTA type B3 fracture of the proximal femur

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Patients younger than 60 years of age
2. Patients with cognitive impairment
3. Patients who are being treated non-operatively
4. Those patients whose responsible Consultant Orthopaedic Surgeon believes would not benefit from THA-S (standard of care)

**Date of first enrolment**

01/05/2013

**Date of final enrolment**

01/05/2014

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

Clinical Sciences Research Laboratories

Coventry

United Kingdom

CV2 2DX

**Sponsor information****Organisation**

University Hospitals Coventry & Warwickshire (UK)

**ROR**

<https://ror.org/025n38288>

**Funder(s)**

Funder type

Industry

**Funder Name**

Orthodynamics (UK)

## 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?
<a href="#">Results article</a>	results	01/11/2016		Yes	No
<a href="#">Protocol article</a>	protocol	02/10/2013		Yes	No