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Warwick Hip Trauma Evaluation Two

Submission date 09/04/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 09/05/2013	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 02/10/2018	**Condition category** Surgery	[_] 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 fracture. 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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Secondary outcome measures
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

Overall study start date
01/05/2013

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

Age group
Adult

Sex
Both

Target number of participants
100

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
England

United Kingdom

Study participating centre
Clinical Sciences Research Laboratories
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation
University Hospitals Coventry & Warwickshire (UK)

Sponsor details
Research, Development & Innovation Department
Clifford Bridge Road
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Sponsor type
Hospital/treatment centre

Website
http://www.uhcw.nhs.uk/

ROR
https://ror.org/025n38288

Funder(s)

Funder type
Industry

Funder Name
Orthodynamics (UK)

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?
Protocol article	protocol	02/10/2013		Yes	No
Results article	results	01/11/2016		Yes	No