ISRCTN39085558 https://doi.org/10.1186/ISRCTN39085558

# The World Hip Trauma Evaluation Study 3: Hemiarthroplasty evaluation multi-centre investigation

**Submission date**
23/09/2014

**Recruitment status**
No longer recruiting

**Registration date**
31/10/2014

**Overall study status**
Completed

**Last Edited**
08/03/2016

**Condition category**
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English Summary

Background and study aims
Fractures of the proximal femur (hip fractures) are a significant medical problem. The number of hip fractures is increasing and is associated with significant problems for both the patient and healthcare providers. About 40 per cent of hip fractures are intra-capsular (within the joint capsule). The blood supply to part of the hip joint is lost and a hip replacement is required. The standard treatment for many of these fractures is hip arthroplasty (replacement); either hemiarthroplasty (replacing half the hip joint) or total hip arthroplasty (replacing the whole hip joint). There is currently debate about which is the best hemiarthroplasty to use. To date, the most commonly used replacement hip implants are the Thompsons stem and the Exeter Trauma Stem. The Thompsons stem has been used extensively in the UK for over 50 years but currently does not have an Orthopaedic Device Evaluation Panel (ODEP rating), a measure of how long the implant lasts, presumably because of there is only a limited amount of information available on them. The recent guidance on hip fracture management recommends the use of proven cemented stem designs with an ODEP rating of at least 3B (97% survival at 3 years), instead of the Thompsons stem. Many clinicians believe the modern characteristics of the Exeter Trauma stem would improve the functioning of the joint after surgery. We want to find out whether there is a difference in the health of patients 4 months after being given a Thompsons Stem hip replacement compared to those given a Exeter stems hip replacement.

Who can participate?
Adults aged at least 60 with a hip fracture and needing a hip hemiarthroplasty.

What does the study involve?
Participants are randomly allocated to receive a Thompsons Stem hip replacement or a Exeter stems hip replacement. They are all asked to fill in a quality-of-life questionnaire 4 months after surgery and clinical assessments are made to compare the two implants.

What are the possible benefits and risks of participating?
There is no specific advantage for patients taking part in the study. However, the information we get from this study should help us to decide which treatment is best to use for patients with this

type of injury in the future. Any operation for a hip fracture carries some risks, but they are the same for both types of hip replacement and are faced by all patients facing a hip replacement. The risks of surgery include the risk of bleeding, risk of blood clots, risk of damage to nerves and blood vessels in the surgical area and the risk associated with the anaesthetic. Patients will have routine X-rays taken of their hip before and after the operation, to evaluate the hip replacement. The dose of radiation they will receive is equivalent to around 2 months of normal background radiation and is the same for all patients who have a hip replacement for a hip fracture.

Where is the study run from?
The study takes place from the following centres in the UK:
1. Northumbria Healthcare NHS Foundation Trust
2. Newcastle Hospitals NHS Foundation Trust
3. South Tees NHS Foundation Trust
4. University Hospitals of Leicester NHS Trust.

When is study starting and how long is it expected to run for?
November 2014 to April 2016.

Who is funding the study?
Stryker (USA)

Who is the main contact?
Mr Mike Reed
mike.reed@nhs.net

# Contact information

### Type(s)
Scientific

### Contact name
Mr Mike Reed

### Contact details
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number
158381

### ClinicalTrials.gov number

### Secondary identifying numbers
Protocol V 2.0 24.07.14; IRAS project ID: 158381

# Study information

### Scientific Title
A randomised controlled trial comparing the Thompsons versus the Exeter® polished taper stem and Unitrax® head in the treatment of displaced intracapsular fractures of the proximal femur

### Acronym
WHiTE 3: HEMI

### Study hypothesis
Null Hypothesis: There is no difference in health status at 4 months post injury between patients over 60 years of age with an AO/OTA type B3 fracture of the proximal femur treated with an Exeter® polished taper/Unitrax® versus a Thompsons.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
NRES committee West Midlands Coventry and Warwickshire; 14/10/2014; ref. 14/WM/1098

### Study design
Multi centre multi-surgeon parallel two arm standard-of-care controlled randomised study

### 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

### Condition
Proximal femur fractures

### Interventions
Hip hemiarthroplasty using either Thompson prosthesis or an Exeter® polished taper with Unitrax® head

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
A validated, patient reported, quality of life questionnaire collected at 4 months post injury  EQ-5D

### Secondary outcome measures
1. Radiological leg length discrepancy
2. Mortality
3. Re-operation and cause
4. Length of index hospital stay
5. Revision at 4 months

### Overall study start date
03/11/2014

### Overall study end date
01/08/2016

## Eligibility

### Participant inclusion criteria
All patients presenting to the collaborative with an AO/OTA type B3 fracture of the proximal femur

### Participant type(s)
Patient

### Age group
Senior

### Sex
Both

### Target number of participants
964

### Participant exclusion criteria
1. Patients younger than 60 years of age
2. Patients with pre-existing symptomatic hip arthritis
3. Patients who are managed non-operatively
4. Patients who the responsible Consultant Orthopaedic Surgeon believe will not benefit from hemiarthroplasty

### Recruitment start date
03/11/2014

**Recruitment end date**
01/08/2016

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Northumbria Healthcare NHS Foundation Trust**
Northumbria
United Kingdom
NE63 9JJ

# Sponsor information

**Organisation**
Northumbria Healthcare NHS Foundation Trust (UK)

**Sponsor details**
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**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/01gfeyd95

# Funder(s)

**Funder type**
Industry

**Funder Name**
Stryker® (USA)

# 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? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |