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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 of protocol

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
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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 objectives
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

Health condition(s) or problem(s) studied
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

Completion date
01/08/2016

Eligibility

Key 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

Key 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

Date of first enrolment
03/11/2014

Date of final enrolment
01/08/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northumbria Healthcare NHS Foundation Trust
Northumbria
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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