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Comparing outcomes of fractured neck of femur patients treated with Thompsons hemiarthroplasty versus Exeter Trauma Stem

Submission date
28/07/2014

Recruitment status
Stopped

Registration date
02/09/2014

Overall study status
Stopped

Last Edited
23/01/2019

Condition category
Injury, Occupational Diseases, Poisoning

[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
When a person has a broken hip, they have a fracture (crack or break) at the top of the thigh bone (femur) nearest to the hip joint. A partial, or half, hip replacement (hemiarthroplasty) is a common, well established, treatment for this condition. Here, we want to compare the performance of two different types of hip replacements, a Thompsons hemiarthroplasty and a Exeter Trauma Stem, and see whether one is better than the other.

Who can participate?
Adults patients aged 65 or over who have a hip fracture that needs to be treated by a hemiarthroplasty.

What does the study involve?
Patients are randomly allocated into one of two groups. Those in group 1 are treated with a Thompsons hemiarthroplasty. Those in group 2 are treated with a Exeter Trauma Stem. After surgery all patients are x-rayed and complete questionnaires. They also receive the usual (standard practice) physiotherapy. Patients are then invited to follow-up clinics at 6 weeks, 3 months and 1 year after their surgery to see how well they are doing and to look out for any complications.

What are the possible benefits/risks of participating?
There may be no direct benefit to any patient taking part in the study. However the information provided by the study will help improve current clinical practice. We do not think there is any increased risk to patients that take part in the study.

Where is the study run from?
Torbay Hospital, South Devon Healthcare NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2014 to September 2015

Who is funding the study?
Torbay Medical Research Fund (UK)

Who is the main contact?
Mr Gordon Higgins
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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
SD-00131

Study information

Scientific Title
Comparing outcomes of fractured neck of femur patients treated with Thompsons hemiarthroplasty versus Exeter Trauma Stem: a randomised controlled trial

Study objectives
Does the Exeter Trauma Stem improve patients mortality, mobility and quality of life compared to the current Thompsons hemiarthroplasty?

Ethics approval required
Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Available on request to sdhct.research@nhs.net

Health condition(s) or problem(s) studied
Trauma & Orthopaedics - Fractured neck of femur

Interventions
Patients diagnosed with a fractured neck of the femur will be randomised into one of two groups. Group 1 will be treated with Thompsons hemiarthroplasty and group 2 with Exeter Trauma stem. They will undergo the following:
1. Non Clinical:
1.1. Pre-operative recruitment, consent and pre-operative questionnaires
1.2. Post-operative functional outcome questionnaire at 1 month, 3 months, and 1 year
2. Clinical:
2.1. Hip Operation (to receive hip hemiarthoplasty)
2.2. Post-operative radiographs (6 weeks, 3 months and 1 year)
2.3. Clinical assessment (6 weeks, 3 months, and 1 year)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Patient related outcome measures (including EQ-5D, SF-36 and Oxford scores) at pre-operation and post operation

Secondary outcome measures
1. Complications post surgery
2. Radiographic appearance of hip implants (post surgery)
3. Patient satisfaction (post surgery)

Overall study start date

30/09/2014

Completion date
29/09/2015

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Patients with intra-capsular fractured neck of femur
2. Patients fit enough for surgery
3. Patients able to give informed consent, or an advocate (unpaid carer/person interested in patient's welfare) is available to grant consent on behalf of the patient
4. Patients > 65 years of age

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Patients unfit for operative intervention
2. Patients who choose not to be included in the trial
3. Patients who are not from the local area and could not attend follow-up
4. Patients who do not speak English and an interpreter is not available at consent
5. Patients who require Total Hip Replacement according to NICE guidelines
6. Where consent for patient or an advocate is not possible
7. Patients < 65 years of age

Date of first enrolment
30/09/2014

Date of final enrolment
29/09/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Trauma and Orthopaedics department
Torquay
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TQ2 7AA

Sponsor information

Organisation
South Devon Healthcare NHS Foundation Trust (UK)

Sponsor details
C/O Manager of Research and Development
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Horizon Centre
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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/05374b979

Funder(s)

Funder type
Research organisation

Funder Name
Torbay Medical Research fund (Project number: 113) (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