

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

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Registration date 02/09/2014	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 23/01/2019	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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 hemiarthroplasty)

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(s)

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

Key secondary outcome(s)

1. Complications post surgery

2. Radiographic appearance of hip implants (post surgery)

3. Patient satisfaction (post surgery)

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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**

United Kingdom

England

Study participating centre

Trauma and Orthopaedics department

Torquay

United Kingdom

TQ2 7AA

Sponsor information**Organisation**

South Devon Healthcare NHS Foundation Trust (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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration