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Comparison of two shoulder replacement methods after trauma

Submission date	Recruitment status	[ ] Prospectively registered
13/01/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/01/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/12/2015	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Injuries to the shoulder joint are common and occur more frequently in elderly patients who fall from standing height. In more severe breaks to the shoulder joint an operation can be performed to prevent pain and deformity. This is often done by replacing the broken head of the joint with a metal ball known as a hemiarthroplasty (shoulder replacement). There is growing debate about the most appropriate treatment of these injuries. There is a newer implant called a reverse total shoulder replacement in which, in addition to replacing the head, the socket is replaced in the shoulder joint. This reverse polarity shoulder replacement has been growing in popularity for treating these injuries. This study compares the results of hemiarthroplasty and reverse total shoulder replacement in severely broken shoulder joints to guide future treatment.

Who can participate?
Adults aged at least 65 years who sustained a severely broken shoulder joint within the last three weeks.

What does the study involve?
Participants are randomly allocated into one of two groups. All participants have shoulder replacement surgery but those in group 1 have a hemiarthoplasty and those in group 2 have a reverse total shoulder replacement. Participants are not told what type of replacement they are having. After surgery, both groups of participants are treated with immobilisation in a sling for four weeks followed by physiotherapy. All participants are seen at six weeks, three months, one year and two years, when they are asked to complete a questionnaire and have an examination. X-rays are also routinely taken during return visits.

What are the possible benefits and risks of participating?
The major benefits of having surgery is that provides good pain relief and function of the shoulder joint for both groups of participants. All the surgical procedures are performed under general anaesthetic. Although anaesthesia is extremely safe with modern techniques, there are still very small risks involved. Some people experience nausea, vomiting and/or dizziness. These are reduced with modern drugs. It is important that participants tell the research team about any medical problems. The surgical procedure itself carries some risks including dislocation of the joint and possibility of further breaks in the bone. There is a small chance of developing

wound infection. This may require treatment with antibiotics. There is also a small risk of damage to the adjacent nerves and vessels in the shoulder.

Where is the study run from?
The study is being run from multiple orthopaedic centres in the UK who are experienced in both the management of these injuries and conducting studies of this kind.

When is the study starting and how long is it expected to run for?
June 2013 to May 2019

Who is funding the study?
Tornier UK Limited (UK)

Who is the main contact?
Professor A C Watts

Contact information

Type(s)
Public

Contact name
Prof Adam Watts

Contact details
Wrightington Hospital
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Wigan
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol 1.9

Study information

Scientific Title
Shoulder Hemiarthroplasty versus Reverse Total Shoulder Arthroplasty for Trauma

Acronym

SHeRPA

Study objectives
There is no difference in outcome at one year for proximal humerus fractures treated with hemiarthroplasty or reverse shoulder arthroplasty.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Committee (REC) North West – Greater Manchester West, 07/05/2013, ref: 12/NW/0724

Study design
Multicentre randomised controlled interventional trial

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
3 or 4 part proximal humerus fractures

Interventions
1. Proximal humerus hemiarthroplasty (intervention 1)
2. Reverse polarity total shoulder arthroplasty (intervention 2)

Intervention Type
Procedure/Surgery

Primary outcome measure
Difference in the mean Constant Score at 12 months post-operatively

Secondary outcome measures
Difference in the mean Constant score, quickDASH score, Oxford shoulder score and ASES score at two years post-operatively

Overall study start date

05/06/2013

Completion date
01/05/2019

Eligibility

Key inclusion criteria
A patient over the age of 65 years within three weeks of a three or four part proximal humerus fracture and who is fit for surgical intervention

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Fifty (50) patients

Key exclusion criteria
1. Dementia
2. Refusal of consent
3. Patient unfit for reverse polarity arthroplasty
4. Glenoid fracture
5. Axillary nerve palsy

Date of first enrolment
01/08/2013

Date of final enrolment
01/05/2017

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Wrightington Wigan and Leigh NHS Trust
Hall Lane

Appley Bridge
Wigan
United Kingdom
WN8 9EP

Study participating centre
Royal Devon and Exeter NHS Foundation Trust
Barrack Road
Exeter
Devon
United Kingdom
EX2 5DW

Study participating centre
Frenchay Hospital, North Bristol NHS Trust
Frenchay Park Road
Bristol
United Kingdom
BS16 1LE

Study participating centre
York Teaching Hospitals NHS Foundation Trust
Wigginton Road
York
North Yorkshire
United Kingdom
YO31 8HE

Study participating centre
Glasgow Royal Infirmary
84 Castle Street
Glasgow
United Kingdom
G4 0SF

Sponsor information

Organisation
Wrightington Hospital

Sponsor details
Research and Development
Hall Lane
Appley Bridge
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WN6 9EP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00y112q62

Funder(s)

Funder type
Industry

Funder Name
Tornier UK Limited

Results and Publications

Publication and dissemination plan

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