Comparison of two shoulder replacement methods after trauma

Submission date	Recruitment status No longer recruiting	Prospectively registered		
13/01/2015		Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
27/01/2015		Results		
Last Edited		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 Hall Lane Appley Bridge Wigan Lancashire United Kingdom WN6 9EP

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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

United Kingdom

England

Scotland

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

ROR

https://ror.org/00y112q62

Funder(s)

Funder type

Industry

Funder Name

Tornier UK Limited

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes