

# Comparison of two shoulder replacement methods after trauma

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<b>Registration date</b> 27/01/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/12/2015	<b>Condition category</b> 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

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 hemiarthroplasty 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 summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No