Prospective randomised study of reverse shoulder prosthesis and hemiarthroplasty for elderly patients with proximal humeral fractures

Submission date	Recruitment status	[X] Prospectively registered
14/03/2007	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
09/05/2007	Completed	☐ Results
Last Edited	Condition category	Individual participant data
11/10/2017	Musculoskeletal Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number 3474

Study information

Scientific Title

Prospective randomised study of Reverse shoulder Prosthesis and Hemiarthroplasty for elderly patients with proximal humeral fractures

Acronym

Reverse Prosthesis vs Hemiarthroplasty

Study objectives

The aim is to find which of the two (Reverse Shoulder Prosthesis or Hemiarthroplasty) is the better prosthesis in the elderly patients, with a shoulder fracture and need for arthroplasty.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Central Office for Research Ethics Committee and Liverpool Local Research Ethics Committee, 10 /10/2007, ref: 07/Q1502/59

Study design

Double-blind randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Elderly patients with shoulder fracture that require arthroplasty

Interventions

Either a Reverse Shoulder Prosthesis or a Hemiarthroplasty for the fracture. All other aspects of treatment including follow up will be the same.

Intervention Type

Procedure/Surgery

Primary outcome(s)

- 1. Activities of daily living of American Shoulder and Elbow Surgeons (ASES)
- 2. Simple shoulder test

These will be measured at one year after the operation

Key secondary outcome(s))

- 1. 36-item Short Form health survey (SF-36)
- 2. University of California and Los Angeles (UCLA) scores
- 3. Radiological outcome

These will be measured at one year after the operation

Completion date

31/05/2008

Eligibility

Key inclusion criteria

- 1. Elderly patients who require arthroplasty for shoulder fracture
- 2. Patients agreeing to participate in the study
- 3. Patients who are able to give consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

- 1. Patients who are younger than 70 years
- 2. Poly-trauma patients
- 3. Multiple fractures
- 4. Open fracture
- 5. Previous operation to the shoulder
- 6. Dementia
- 7. Nerve or vessel injury
- 8. Unable to understand English

Date of first enrolment

01/06/2007

Date of final enrolment

31/05/2008

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Royal Liverpool and Broadgreen University Hospitals

Liverpool United Kingdom L7 8XP

Sponsor information

Organisation

Royal Liverpool and Broadgreen University Hospital NHS Trust (UK)

ROR

https://ror.org/009sa0g06

Funder(s)

Funder type

Government

Funder Name

Royal Liverpool and Broadgreen University Hospital NHS Trust (UK)

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?

Participant information sheet Participant information sheet 11/11/2025 11/11/2025 No Yes