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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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 to request a patient information sheet

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 measure

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

Secondary outcome measures
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

Overall study start date
01/06/2007

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

Age group
Senior

Sex
Both

Target number of participants
120

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
England

United Kingdom

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)

Sponsor details
Prescot Street
Liverpool
England
United Kingdom
L7 8XP

Sponsor type
Hospital/treatment centre

Website
http://www.rlbuht.nhs.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration