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

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 humaral 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 planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration