

Shoulder Arthroplasty Trial

Submission date 12/12/2012	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 12/12/2012	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 16/11/2016	Condition category Musculoskeletal Diseases	☐ Individual participant data
		☐ 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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Additional identifiers

Protocol serial number

11130

Study information

Scientific Title

A randomised controlled trial of total resurfacing versus hemi resurfacing in the treatment of primary osteoarthritis of the shoulder

Study objectives

A randomised controlled trial of total resurfacing versus hemi resurfacing in the treatment of primary osteoarthritis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

First MREC, 30/08/2011, ref: 11/WM/0245

Primary study design

Interventional

Study design

Non-randomised interventional study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Musculoskeletal disease

Interventions

Hemi Resurfacing Arthroplasty:

The humeral head is resurfaced and the glenoid remains intact with no surgical intervention

Total Resurfacing Arthroplasty:

Total Resurfacing Shoulder Arthroplasty. The glenoid and humeral head is resurfaced.

Followed up at 12 months

Intervention Type

Procedure/Surgery

Primary outcome(s)

Oxford Shoulder Score, measured at baseline, 6 weeks, 3 months, 6 months and 12 months

Key secondary outcome(s)

No secondary outcome measures

Completion date

30/04/2014

Eligibility

Key inclusion criteria

1. Patient has severe osteoarthritis of the shoulder
2. Patient is suitable for a total resurfacing of the shoulder

3. Patient is medically fit for surgery
4. Patients aged 18 years of age or older
5. Male or female participants

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Patients unlikely to be able to adhere to trial procedures
2. Patients not able to provide informed consent

Date of first enrolment

31/01/2012

Date of final enrolment

30/04/2014

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

University of Warwick

Coventry

United Kingdom

CV2 2DX

Sponsor information**Organisation**

University of Warwick (UK)

ROR

<https://ror.org/01a77tt86>

Funder(s)

Funder type

Government

Funder Name

NIHR Research for Patient Benefit Programme (UK) (ref: PB-PG-0110-21121)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration