ISRCTN18607924 https://doi.org/10.1186/ISRCTN18607924

Shoulder Arthroplasty Trial

Submission date
12/12/2012

Recruitment status
No longer recruiting

Registration date
12/12/2012

Overall study status
Completed

Last Edited
16/11/2016

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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
Prof Damian Griffin

Contact details
University of Warwick
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX
-
damian.griffin@warwick.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Non-randomised interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

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

Secondary outcome measures
No secondary outcome measures

Overall study start date
31/01/2012

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 30

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
England

United Kingdom

Study participating centre
University of Warwick
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation
University of Warwick (UK)

Sponsor details
Gibbet Hill Road
Coventry
England
United Kingdom
CV4 7AL

Sponsor type
University/education

Website
http://www2.warwick.ac.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

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