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Early stability and clinical outcomes of the LIMA Stemless Reverse Shoulder Replacement assessed using x-ray analysis, clinical follow-up and patient-reported outcomes

Submission date
13/09/2022

Recruitment status
No longer recruiting

Registration date
21/09/2022

Overall study status
Completed

Last Edited
08/12/2022

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study will be the first known study to investigate the stability and outcomes of the LIMA stemless humeral component in total reverse shoulder arthroplasty (one of the replacement parts for the bony ball and socket joint of the shoulder). The stability of this component will be evaluated using radiostereometric analysis (RSA), a special x-ray technique which allows observation and measurement of very small movements (migrations) over a 2-year postoperative period.

Who can participate?
Patients over the age of 55 years with concentric glenohumeral (shoulder) osteoarthritis

What does the study involve?
All participants will have surgery with a LIMA reverse glenoid and the stemless humeral component which are part of the Shoulder Modular System (LIMA Corporate, Italy). At the time of listing for surgery, if the surgeon considers the use of this type of shoulder replacement clinically appropriate, the patient will be invited to participate in this study. If the patient is willing to consider participation, a participation information sheet will be provided and the patient is given the opportunity to discuss this and ask questions with the research staff. During the clinical visit, pre-operative information, including clinical and patient-reported data, will be collected as part of routine care. Written consent to participate in the study will then be sought in person at either a follow-up clinic visit or at a pre-op assessment. Final confirmation of willingness to participate in the RSA study will be affirmed by the surgeon on the ward during the booking in process. The research team will be available to address any further questions and complete any study documentation. Plain x-ray and CT scanning are routinely used preoperatively in patients being assessed for shoulder arthroplasty. The first postoperative RSA image will be obtained within 1 week of implantation (usually while the patient is still an in-patient) and the patient will be followed up with RSA images and data collection at 3 months, 6 months, 12 months and 2 years.

What are the possible benefits and risks of participating?
Risks include some increase in radiation dose to the patient. Standard surgical risks apply. All implants to be used are approved for human use in the UK. Potential benefits include preservation of host bone stock and prevention of stress shielding.

Where is the study run from?
Wrightington, Wigan & Leigh Teaching Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
August 2021 to February 2025

Who is funding the study?
LimaCorporate (Italy)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
299318

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 50609, IRAS 299318

Study information

Scientific Title
A study of the performance of the novel LIMA stemless reverse humeral replacement; a prospective radio-stereometric analysis study of the magnitude and pattern of migration of humeral components

Study objectives
In patients over the age of 60, with painful rotator cuff arthropathy of the glenohumeral joint, the LIMA stemless humeral component has acceptable short-term stability.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/12/2021, West Midlands - Solihull Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8191, +44 (0)207 104 8269; solihull.rec@hra.nhs.uk), ref: 21/WM/0227

Study design
Non-randomized; Interventional; Design type: Treatment, Imaging, Surgery

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
Concentric glenohumeral osteoarthritis

Interventions
Participants will be invited to participate at the time of listing for surgery and pre-operative information, including clinical and patient-reported data, will be obtained after fully informed consent is given. Plain x-ray and CT scanning are routinely used preoperatively in patients being assessed for shoulder arthroplasty. The first postoperative RSA image will be obtained within 1 week of implantation and the patient will be followed up with RSA images and data collection at 3 months, 6 months, 12 months and 2 years.

Intervention Type
Other

Primary outcome measure
The magnitude and pattern of migration of the LIMA hybrid anatomic glenoid component measured using model-based RSA over a minimum period of 2 years

Secondary outcome measures
1. Clinical and patient-reported outcomes collected using the Shoulder Pain and Disability Index (SPADI) questionnaire from pre-op to 2 years
2. Adverse events, implant survival and need for surgical revision", collected by the direct care team at clinical visits and by the research team at follow-up visits if this does not coincide with a clinical visit, monitored over a minimum of 2 years

Overall study start date
12/08/2021

Completion date
28/02/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 19/10/2022:
1. Male and female patients
2. Concentric glenohumeral osteoarthritis
3. Glenoid suitable for non-augmented anatomical component (Walch A or B1)
4. Intact rotator cuff

Previous inclusion criteria:
1. Male and female patients over the age of 55 years
2. Concentric glenohumeral osteoarthritis
3. Glenoid suitable for non-augmented anatomical component (Walch A or B1)
4. Intact rotator cuff

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 20; UK Sample Size: 20

Key exclusion criteria
1. Inability to consent
2. Inflammatory arthropathy
3. Sequelae of trauma
4. Patients who are unable to attend follow-up for imaging and required assessment (due to the need to access specialist equipment at Wrightington for the RSA imaging)

Date of first enrolment
14/06/2022

Date of final enrolment
14/06/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wrightington Hospital
Hall Lane
Appley Bridge
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United Kingdom
WN6 9EP

Sponsor information

Organisation
Wrightington, Wigan and Leigh NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.wwl.nhs.uk/

ROR
https://ror.org/028mrxf52

Funder(s)

Funder type
Industry

Funder Name
LimaCorporate spa

Results and Publications

Publication and dissemination plan
The information gathered in the study will be published and peer-reviewed in scientific research journals and discussed at scientific conferences. Preliminary results will be available after 2 years and final results are expected within 4 years.

Intention to publish date
28/02/2027

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No