ISRCTN12216466 https://doi.org/10.1186/ISRCTN12216466

Reverse or Anatomical replacement for Painful Shoulder Osteoarthritis, Differences between Interventions (RAPSODI-UK)

Submission date
13/07/2022

Recruitment status
Recruiting

Registration date
13/07/2022

Overall study status
Ongoing

Last Edited
11/04/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
The aim of this study is to find the best type of joint replacement for the treatment of painful osteoarthritis of the shoulder.

With increasing age, shoulder osteoarthritis is common and causes severe pain and stiffness making everyday activities difficult. A shoulder replacement is an effective solution, reducing pain and allowing the shoulder to move better. The operation replaces damaged bone with new metal and plastic parts. There are two types of shoulder replacement:
1. Anatomic Total Shoulder Replacement which relies on the tendons (Rotator Cuff) around the shoulder to be intact and healthy
2. Reverse Total Shoulder Replacement, which is usually used when the rotator cuff becomes weaker or torn

The rotator cuff can weaken with age which may cause an anatomic replacement to stop working. This could mean a further operation to change the shoulder to a reverse total shoulder replacement. For this reason, an increasing number of patients are offered reverse shoulder replacements even when their rotator cuff is intact. Currently, there is no scientific evidence to support this change and no guidance to recommend which is the best type of shoulder joint replacement. We will investigate which type of surgery gives value for money and the best outcome.

The local PPI Group played a central role in designing this study. They felt that this is an important question to answer and that with surgery it is vital to get ‘it’ right the first time both for the patient and for economic reasons. We, therefore, asked 34 surgeons in a survey about their practice and found 87% already perform or would consider a reverse shoulder in patients with an intact rotator cuff and 74% would be willing to change practice based on the results of the study evidence. Fourteen people who are volunteers for the hospital completed a survey containing a study information sheet. Thirteen said that they would consider being randomised to a study of this type. The PPI group influenced the choice of outcome measure and suggested the addition of a linked qualitative study. A member of the group has agreed to be a co-

applicant for the study. All participant documentation will be written with input from the PPI group, strengthened with support from diversity and inclusion experts.

Who can participate?
People over the age of 60 who would benefit from a shoulder replacement and have an attached working rotator cuff will be asked to take part in the study.

What does the study involve?
Before their operation, participants will fill in questionnaires about pain and function. At the time of surgery, the type of replacement given will be decided by a process called randomisation. This means that the patient may be allocated to have either an anatomic or reverse total shoulder replacement with equal chance of either type of replacement (like tossing a coin). Participants will not know which treatment group they are in until the end of the study. Clinic visits after the operation will happen as normal but with the addition of remote questionnaires at 3, 6, 12, 18 and 24 months. A subgroup of about 20 participants will be interviewed at 2 and 12 months after their operations to share experiences and thoughts about their recovery.

What are the possible benefits and risks of participating?
Shoulder replacements can only be improved with the help of patients. So taking part in this study means that patients may help improve the care of future patients who need shoulder replacements. Patients may also have more support taking part in the study because of the wider team involved. There is no increased risk for patients taking part in the study. The NHS has treated patients with the types of shoulder replacements being compared in this study for many years. Patients taking part will face the same risks of surgery and receive the same care as patients who have one of these shoulder replacements without taking part in the study. Any adverse events that patients taking part may experience will be followed-up according to regulatory requirements.

Where is the study run from?
Wrightington, Wigan, and Leigh Teaching Hospitals NHS Foundation Trust (UK) in collaboration with York Trials Unit (UK)

When is the study starting and how long is it expected to run for?
From March 2022 to April 2027

Who is funding the study?
National Institute for Health Research (NIHR) Health Technology Assessment (HTA) (UK)

Who is the main contact?
The study team can be contacted at ytu-rapsodi@york.ac.uk

Study website
https://www.york.ac.uk/healthsciences/research/trials/research/trials/rapsodi/

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
313848

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
NIHR133418, CPMS 53735

Study information

Scientific Title
Reverse or Anatomical replacement for Painful Shoulder Osteoarthritis, Differences between Interventions (RAPSODI-UK): a multi-centre, pragmatic, parallel group, superiority randomised controlled trial

Acronym
RAPSODI-UK

Study objectives
In patients aged 60 years and over, with painful OA of the shoulder with an intact rotator cuff and suitable bone stock, is reverse total shoulder replacement (rTSR) superior, in terms of clinical and cost-effectiveness, to anatomical total shoulder replacement (aTSR)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/10/2022, London - Queen Square Research Ethics Committee (HRA NRES Centre Bristol, 3rd floor, block B Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 1048225, (0) 207 1048284; queensquare.rec@hra.nhs.uk), ref: 22/LO/0617

Study design
Pragmatic, patient and assessor-blinded, multi-centre, parallel-group, superiority randomized controlled trial with a full health economic evaluation, data linkage with the National Joint Registry, and an embedded qualitative interview study

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 contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Painful osteoarthritis of the shoulder joint

Interventions
Eligible and consenting patients will be randomly allocated to either anatomical total shoulder replacement (aTSR) or reverse total shoulder replacement (rTSR). Only non-augmented replacements will be used. Therefore, patient specific implants that are custom made to an individual's anatomical specifications will not be allowed.

Intervention:
For the rTSR, the arrangement of the ball and socket component parts are reversed making use of the deltoid muscle for movement of the arm: it does not rely on an intact or functioning rotator cuff.

Comparator:
The aTSR is a conventional shoulder replacement which mimics the natural ball and socket structure of the joint and relies on the presence of an intact rotator cuff for useful range of movement. The choice of implant will depend on local practice at recruiting sites but will include any anatomical shoulder implant from any manufacturer licensed for use in the UK implanted using techniques consistent with manufacturer instructions.

Randomisation:
Allocation will be 1:1, using random permuted blocks of random block size, stratified by age (60-69; 70+) as a surrogate of deteriorating shoulder rotator cuff function. The allocation schedule will be generated by a trial statistician, otherwise not involved in the recruitment or randomisation of participants. It will be implemented using a secure web-based randomisation service managed by York Trials Unit (YTU), ensuring allocation concealment. The research team at the site will confirm patient eligibility and consent and access the online service to perform the randomisation ideally two weeks before surgery but no earlier than the pre-operative clinic to confirm the patient is fit for surgery.

Intervention Type
Procedure/Surgery

Primary outcome measure
Patient-reported shoulder pain and function measured using combined Shoulder Pain and Disability Index (SPADI) score at 24 months

Secondary outcome measures
1. Pain and function measured using total SPADI score at 3, 6, 12, 18, and 24 months
2. Quality of life measured using individual subscales of pain and disability from SPADI, Oxford Shoulder Score (OSS), and EuroQol 5-dimension 5-level (EQ-5D-5L) questionnaires at 3, 6, 12, 18 (SPADI only) and 24 months

3. Resource use measured using a patient-reported questionnaire at 3, 6, 12, and 24 months
4. Re-operations and complications measured from medical records at 3, 6, 12, and 24 months
5. Objective assessments using shoulder range of movement and strength and global shoulder score at 24 months
6. Revisions and mortality measured from medical records at 24 months.

Overall study start date
01/03/2022

Completion date
30/04/2027

Eligibility

Key inclusion criteria
1. Aged ≥60 years
2. Diagnosis of painful osteoarthritis of the glenohumeral joint using routine radiographs not controlled by previous interventions
3. An intact rotator cuff determined by pre-operative advanced imaging (Ultrasound, MRI, or CT)
4. Minimal glenoid erosion determined by pre-operative CT or other imaging in whom a non-augmented replacement is appropriate
5. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
60 Years

Sex
Both

Target number of participants
430

Key exclusion criteria
1. Shoulder replacement surgery contra-indicated
2. A diagnosis of inflammatory arthritis, acute trauma or trauma sequelae
3. Evidence that the patient would be unable to adhere to trial procedures or complete questionnaires
4. Trial participant for TSR for opposite shoulder

Date of first enrolment
01/11/2022

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
England

Northern Ireland

United Kingdom

Wales

Study participating centre
Wrightington Hospital NHS Trust
Hall Lane
Wrightington
Wigan
United Kingdom
WN6 9EP

Study participating centre
Airedale General Hospital
Skipton Road
Steeton
Keighley
United Kingdom
BD20 6TD

Study participating centre
Musgrave Park Hospital
Stockmans Ln
Belfast
United Kingdom
BT9 7JB

Study participating centre
Royal Berkshire Hospital
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre
Sandwell and West Birmingham Hospitals NHS Trust
City Hospital
Dudley Road
Birmingham
United Kingdom
B18 7QH

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
West Suffolk Hospital
Hardwick Ln
Bury Saint Edmunds
United Kingdom
IP33 2QZ

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
St James's University Hospital
St James's University Hospital
Gledow Wing
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre

Countess of Chester Hospital
Countess of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1UL

Study participating centre
Chesterfield Royal Hospital
Chesterfield Road
Calow
Chesterfield
United Kingdom
S44 5BL

Study participating centre
Colchester General Hospital
Colchester District General Hosp.
Charter Way
Turner Road
Colchester
United Kingdom
CO4 5JL

Study participating centre
University Hospital Coventry
University Hospital Coventry
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre

Prince Phillip Hospital
Bryngwyn Mawr
Llanelli
United Kingdom
SA14 8QF

Study participating centre
Ipswich Hospital
Heath Road
Ipswich
United Kingdom
IP4 5PD

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Broadgreen Hospital
Thomas Drive
Liverpool
United Kingdom
L14 3LB

Study participating centre
Trafford General Hospital
Trafford General Hospital
Moorside Road
Urmston
Manchester
United Kingdom
M41 5SL

Study participating centre
Milton Keynes University Hospital
Standing Way
Eaglestone
Milton Keynes

United Kingdom
MK6 5LD

Study participating centre
Furness General Hospital
Dalton Lane
Barrow-in-furness
United Kingdom
LA14 4LF

Study participating centre
Musgrove Park Hospital (taunton)
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
North Tyneside General Hospital
North Tyneside General Hospital
Rake Lane
North Shields
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NE29 8NH

Study participating centre
Nottingham City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Nuffield Orthopaedic Centre
Windmill Road
Headington
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OX3 7HE

Study participating centre
Peterborough City Hospital
Edith Cavell Campus
Bretton Gate
Bretton
Peterborough
United Kingdom
PE3 9GZ

Study participating centre
Northern General Hospital
Northern General Hospital NHS Trust
C Floor, Huntsmnan Building
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Royal National Orthopaedic Hospital
Brockley Hill
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United Kingdom
HA7 4LP

Study participating centre
Princess Royal Hospital
Lewes Road
Haywards Heath
United Kingdom
RH16 4EX

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

Study participating centre
Yeovil District Hospital
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BA21 4AT

Sponsor information

Organisation
Wrightington, Wigan and Leigh NHS Foundation Trust

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Hall Lane
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Helen.Spickett@wwl.nhs.uk

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/028mrxf52

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The executive summary and copy of the trial report will be sent to NICE and other relevant bodies, including to Integrated Care Systems, so that the study findings can inform their deliberations and be translated into clinical practice nationally. We will also work with the relevant National Clinical Director in the Department of Health to help ensure the findings of the trial are considered when implementing policy and will work with the Specialty Advisory Committees (SAC) to incorporate the findings into the training curriculum for clinicians who will undertake shoulder arthroplasty. The British Elbow and Shoulder Society have adopted the trial into their research portfolio which will facilitate dissemination of findings to relevant stakeholders. There are planned publications in a high-impact peer-reviewed journals and at national and international conferences.

Intention to publish date
01/10/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the trial team (ytu-rapsodi@york.ac.uk). Anonymised data will be shared for secondary analyses including meta-analyses. Consent from participants was obtained to allow the sharing of their data with other researchers in other institutions such that they could not be identified in any data released.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (other)		24/04/2023	29/08/2024	No	No