ISRCTN97804283 https://doi.org/10.1186/ISRCTN97804283

United Kingdom Rotator Cuff Trial

Submission date	Recruitment status	[X] Prospectively registered
22/06/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/06/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/12/2017	Musculoskeletal Diseases	

Plain English summary of protocol
http://www.ndorms.ox.ac.uk/clinicaltrials.php?trial=rotcuffsur

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 05/47/02; Version 4, 25/08/10

Study information

Scientific Title
Clinical effectiveness and cost-effectiveness of open and arthroscopic rotator cuff repair

Acronym
UKUFF

Study objectives
Current information as of 21/10/10:

Initial information at time of registration:
To assess the clinical and cost effectiveness of three treatments for rotator cuff tears - surgical (arthroscopic or open repair) versus non-surgical management.

Please note that as of 21/10/10 this record has been updated to reflect changes in the trial protocol from a 3-arm to a 2-arm trial. More details can be found in the relevant fields with the above update date. Please also note that the anticipated end date of the trial has been extended from 30/06/12 to 31/12/13.

More details at http://www.hta.ac.uk/project/1551.asp
Protocol available at http://www.hta.ac.uk/protocols/200500470002.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current information as of 21/10/10:
Multi-centre Research Ethics Committee (MREC) approved on the 15th of April 2010 (ref: 07 /Q1606/49)

Initial information at time of registration:
Multi-centre Research Ethics Committee (MREC) approved on the 12th of June 2007 (ref: 07 /Q1606/49)

Primary study design
Interventional

Study design
Parallel-group randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Musculoskeletal Diseases

Interventions
Current information as of 21/10/10:
Each participant will be randomised to one of the following arms:
Arm 1 - Open/mini-open surgery
Arm 2 - Arthroscopic surgery

Initial information at time of registration
Each participant will be randomised to one of the following arms:
Arm 1: Arthroscopic surgery
Arm 2: Open surgery
Arm 3: Rest then Exercise Programme

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The UKUFF Questionnaire at 24 months after entry into study.

Key secondary outcome(s)
Resource use measures including use and cost of health services.

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Aged 50 years or older
2. Suffer from degenerative rotator cuff tear
3. Have full thickness rotator cuff tear
4. Tear diagnosed using Magnetic Resonance Imaging (MRI) or ultrasound scan
5. Patient able to consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Previous surgery on affected shoulder
2. Dual shoulder pathology
3. Significant problems in other shoulder
4. Rheumatoid arthritis / systemic disease
5. Significant osteoarthritis problems
6. Significant neck problems
7. Cognitive impairment or language issues

Date of first enrolment
01/07/2007

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Windmill Road
Oxford
United Kingdom
OX3 7LD

Sponsor information

Organisation
University of Oxford (UK)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	surgeon questionnaire results	01/06/2012		Yes	No
Results article	complete study results	01/10/2015		Yes	No
Protocol article	protocol	01/05/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes