

United Kingdom Rotator Cuff Trial

Submission date 22/06/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 29/06/2007	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 05/12/2017	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://www.ndorms.ox.ac.uk/clinicaltrials.php?trial=rotcuffsur>

Contact information

Type(s)

Scientific

Contact name

Ms Cushla Cooper

Contact details

Windmill Road
Headington
Oxford
United Kingdom
OX3 7LD
+44 (0)1865 737643
cushla.cooper@ndorms.ox.ac.uk

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)

Study design

Parallel-group randomised controlled trial

Primary study design

Interventional

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