

# United Kingdom Rotator Cuff Trial

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

## Plain English summary of protocol

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

## Study website

<http://www.charttrials.abdn.ac.uk/ukuff>

## 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](mailto:cushla.cooper@ndorms.ox.ac.uk)

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## **Participant information sheet**

Patient Information Sheet version 6 dated 19/01/2010 is available for download from <https://viis.abdn.ac.uk/HSRU/UKUFF/Site/Public/DownloadPage.aspx>

## **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 measure**

The UKUFF Questionnaire at 24 months after entry into study.

## **Secondary outcome measures**

Resource use measures including use and cost of health services.

## **Overall study start date**

01/07/2007

## **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

## **Age group**

Senior

**Sex**

Both

**Target number of participants**

As of 21/10/10: 270 (at time of registration: 690)

**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**

England

United Kingdom

**Study participating centre**

**Windmill Road**

Oxford

United Kingdom

OX3 7LD

## **Sponsor information**

**Organisation**

University of Oxford (UK)

**Sponsor details**

Clinical Trials and Research Governance

Manor House

John Radcliffe Hospital

Headington  
Oxford  
England  
United Kingdom  
OX3 9DZ  
+44 1865 743004  
heather.house@admin.ox.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.admin.ox.ac.uk/rso>

**ROR**

<https://ror.org/052gg0110>

## Funder(s)

**Funder type**

Government

**Funder Name**

NIHR Health Technology Assessment Programme - HTA (UK)

## 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	surgeon questionnaire results	01/06/2012		Yes	No
<a href="#">Protocol article</a>	protocol	01/05/2014		Yes	No
<a href="#">Results article</a>	complete study results	01/10/2015		Yes	No

