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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

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

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?
Results article	surgeon questionnaire results	01/06/2012		Yes	No
Protocol article	protocol	01/05/2014		Yes	No
Results article	complete study results	01/10/2015		Yes	No