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Concomitant Biceps Tenodesis in Primary Shoulder Arthroplasty for Primary Osteoarthritis - A Randomised Controlled Study

Submission date	Recruitment status	[ ] Prospectively registered
28/09/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/09/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/06/2013	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0227186094

Study information

Scientific Title

Study objectives
What is the effect of concomitant biceps tenodesis in primary shoulder arthroplasty done for primary osteoarthritis? Does it improve or worsen the pain relief and function of the new shoulder joint or it has no effect? This project aims to produce a level I evidence for this question at 2 and 5 years follow up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
DESIGN OF STUDY - This is a prospective randomised controlled study recruiting patients who have been wait listed for primary shoulder replacement operation for primary shoulder osteoarthrosis at JCUH. These patients will be given all the information about the study at least 2 weeks prior to operation and those patients willing to participate in the study will be consented and recruited into the study.

PILOT STUDY - Since the surgeon is experienced and has been performing biceps tenodesis in addition to shoulder replacement operations in certain selected cases, the pilot study has not been planned.

TRIAL PHASE - Once the trial phase begins all the patients who are listed as candidates for primary shoulder operation for Primary Osteoarthritis are assessed by an independent observer

in the clinic. The patients are given information leaflet about the condition he or she has got, about the study being performed and blinded allocation of patients into two groups "with or without concomitant biceps tenodesis at the time of Primary shoulder replacement operation". Any questions from the patients will also be clarified. Address and telephone number for further help and information is also given in the information leaflet. For selecting the surgical procedure, a blinded randomisation will be performed using the SPSS soft ware (SPSS, Chicago, IL). The code of the procedure (1. Concomitant Biceps tenodesis 2. No concomitant biceps tenodesis) will be revealed to surgeon at the time of operation. The anaesthesia, surgical approach, post operative pain management and rehabilitation will be exactly same between both groups. A standardised prostair is used in all cases. Tenodesis of long head of biceps is only an additional step, where in the tendon will be divided and sutured into its bony tunnel, around its sheath by means of 2-3 interrupted non absorbable sutures. This step of operation needs no additional exposure of the wound nor it takes longer than 3-4 mins when performed. Patients and the single independent observer will be blinded as to the procedure performed until the end of the study. Patients are followed up at 6 weeks, 3 months, 6 months post op and yearly thereafter. All the clinical and radiographic data documented in a specifically designed data collection form. Data will be regularly entered into spread sheets using SPSS software. Analysis of the various demographic, functional and radiological data including Oxford and Constant scores will be done at 1 year, 2 years, 5 years follow up.

SURGEONS PERFORMING THE PROCEDURES - The number of surgeons performing to the procedure will be limited to 2-3 over the study period and all operations will be performed in the presence of a senior consultant orthopaedic surgeon at JCUH.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
During the pre op and various stages of post operative phases, demographic details will be collected. A patient questionnaire (based on Oxford score) which will give information about pain and functional abilities.Assessment using Constant and Murley score which looks at assessment of daily activities (score), assessment of external rotation and internal rotation (score for each movement), assessment of forward elevation and lateral elevation (score for various degrees of movement), pain level (scored 0, 5, 10, 15), level of raising the hand (up to waist, xiphoid, neck, up to the head, above the head, unable to move shoulder), shoulder power (measured by a special device).

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/2006

Completion date
01/02/2011

Eligibility

Key inclusion criteria
The study intends to examine all the patients with painful, primary degenerative glenohumeral joint who are listed to undergo a Primary Shoulder Replacement. It would involve patients from both sexes and all age groups. We have not sought for any statistical help yet for calculating the required sample size. It is expected to include at least 25 patients from each of the two operation groups. Statistical consultation has been requested.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
50

Key exclusion criteria
1. Patients with rheumatoid or other inflammatory arthritis
2. Patients who had previous operations for trauma or infection in the same joint
3. Neurovascular problems
4. Revision operations
5. Patients with history of previous instability problems of the shoulder
6. Patients with rotator cuff deficiency
7. Patients with previous biceps tendon rupture
8. However, the patient or assessor would be kept blind to whether concomitant biceps tenodesis procedure is performed.

Date of first enrolment
01/02/2006

Date of final enrolment
01/02/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Orthopaedics
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

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Funder(s)

Funder type
Government

Funder Name
South Tees Hospitals NHS Trust (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