

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

Submission date 28/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/06/2013	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 osteoarthritis 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 prosthesis 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

Middlesbrough

United Kingdom

TS5 5AZ

Sponsor information

Organisation

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

Sponsor details

The Department of Health, Richmond House, 79 Whitehall
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Sponsor type

Government

Website

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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