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A randomized placebo controlled clinical trial of a rehabilitation programme for patients with a diagnosis of massive, irreparable rotator cuff tears of the shoulder

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
28/03/2012

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0620168697

Study information

Scientific Title

Study objectives
To investigate the effect of a specific rehabilitation programme for patients with massive tears of the rotator cuff tendons in their shoulder.

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)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Musculoskeletal Diseases: Shoulder disorders

Interventions
Patients will be randomized to receive ultrasound or to receive ultrasound and a rehabilitation program. Patients randomized into the rehabilitation arm of the study will be following the rehabilitation program developed at Torbay hospital.

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
To use the information collected to improve the rehabilitation programme and to increase awareness of which patient will do well with the programme.
Primary outcome measure: Oxford Shoulder Score.

Secondary outcome measures
Not provided at time of registration

Overall study start date
05/09/2005

Completion date
31/08/2008

Eligibility

Key inclusion criteria
60 patients with a diagnosis of irreparable rotator cuff tears will be recruited from patients referred into the South Devon Physiotherapy Service by GPs, consultants or by self referral, 30 for the exercise group and 30 for the control group.
Inclusion criteria:
1. 18 years or over (no upper age limit)
2. Male or female
3. Clinical and ultrasonographic diagnosis of massive rotator cuff tear (full thickness tear of more than 5cm)
4. Diagnosis of massive, irreparable rotator cuff tear following shoulder surgery to try to repair the rotator cuff
5. Patient able to understand and co-operate with research and able to give informed consent
6. Fluent in written and spoken English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria

1. Diagnosed neurological abnormality affecting the shoulder joint complex
2. Patients involved in an industrial claim or litigation
3. Patients whose rotator cuff tear is considered to be operable

Date of first enrolment
05/09/2005

Date of final enrolment
31/08/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Consultant Physiotherapist
Torquay
United Kingdom
TQ2 7AA

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Exeter Primary Care Trust (UK)

Funder Name
NHS R&D Support Funding (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	results	01/09/2006		Yes	No