

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	<input type="checkbox"/> Prospectively registered
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/03/2012	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mrs Roberta Ainsworth

Contact details

Consultant Physiotherapist
Physiotherapy Department
Torbay Hospital
Torquay
United Kingdom
TQ2 7AA
+44 01803 655340
roberta.ainsworth@nhs.net

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

Study participating centre

Consultant Physiotherapist

Torquay

United Kingdom
TQ2 7AA

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

Exeter Primary Care Trust (UK)

Funder Name

NHS R&D Support Funding (UK)

Results and Publications

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