

A prospective, controlled randomised study investigating functional outcome, with early and late physiotherapy, on patients following a fractured proximal humerus.

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/12/2008	Condition category Injury, Occupational Diseases, Poisoning	<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

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RBF 98X42

Study information

Scientific Title

Study objectives

To examine the functional outcome of patients sustaining a fractured proximal humerus, following early and late physiotherapy.

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)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Injury, occupational diseases, poisoning: Musculoskeletal injury

Interventions

- 1.. Physiotherapy within one week of their interviews
2. Physiotherapy at three weeks following their injury.

Both groups will receive treatment by senior physiotherapists who will be following a physiotherapy protocol for treatment and home exercises. Functional outcome measurements will be taken at three intervals.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Outcome measure: SF-36 and C-MSA (Constant-Murley shoulder assessment)

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/1998

Completion date

30/04/2001

Eligibility

Key inclusion criteria

120 patients sustaining fractured proximal humerus

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

120

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/10/1998

Date of final enrolment

30/04/2001

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Orthopaedics
Sheffield
United Kingdom
S5 7AU

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

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.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive Trent (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	01/04/2003		Yes	No
Results article	2 -year follow-up results	01/03/2007		Yes	No