

The Optimal Conservative Management of Isolated Midshaft Clavicle Fractures

Submission date
30/09/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
30/09/2005

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
25/04/2014

Condition category
Injury, Occupational Diseases, Poisoning

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr N Talbot

Contact details
The Old Dairy
Fore Street
Silverton
Exeter
United Kingdom
EX5 4HP

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0185146336

Study information

Scientific Title

Study objectives

Prospectively how do the clinical, radiological and functional outcomes of two well established methods of immobilising clavicle fractures compare? One method immobilises the arm on the affected side whereas the other (figure of eight shoulder bandage) leaves both arms free and may therefore interfere less with activities of daily living.

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: Clavicle fractures

Interventions

Patients fulfilling inclusion criteria will be given an information leaflet in casualty. Those agreeing to enter the trial will be randomised by opening an envelope to either the sling or shoulder brace group. They will be followed up in the fracture clinic at 3 & 8 weeks and x-rayed as normal but will complete a short questionnaire at the end of each week and answer a short questionnaire at their 8 week clinic visit.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Patient completed questionnaire relating to activities of daily living and pain scores. Clinical, cosmetic and radiological outcome.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/2002

Completion date

01/07/2003

Eligibility

Key inclusion criteria

100 patients (50 in each of the two treatment arms) with isolated closed diaphyseal (midshaft) fractures of clavicle.

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

100

Key exclusion criteria

1. Age below 18 or above 65
2. Mentally incompetent
3. Not resident locally

Date of first enrolment

01/04/2002

Date of final enrolment

01/07/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
The Old Dairy
Exeter
United Kingdom
EX5 4HP

Sponsor information

Organisation
Department of Health

Sponsor details
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
Plymouth Hospitals NHS Trust (UK), Own Account

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