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The Optimal Conservative Management of Isolated Midshaft Clavicle Fractures

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/04/2014	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 fulfulling 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
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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