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Splintage In External Rotation For Anterior Glenohumeral Dislocation: A Prospective, Randomised & Controlled Study

Submission date	Recruitment status	[ ] Prospectively registered
28/09/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/09/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/06/2013	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
N0649183954

Study information

Scientific Title

Study objectives
Does splintage in external rotation following anterior shoulder dislocation reduce the incidence of recurrent dislocation?

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Injury, Occupational Diseases, Poisoning: Shoulder dislocation

Interventions
Patients presenting to fracture clinic with a first time shoulder dislocation are randomised to either current practice (use of sling) or use of an external rotation splint. Treatment otherwise is identical.

Queen Elizabeth Hospital NHS Trust study also ongoing at East Kent Hospitals which now makes it a dual centre study. Both local and central ethical approval has been gained for this.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

The only outcome measure needed is the incidence of recurrent dislocation.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2005

Completion date
01/11/2010

Eligibility

Key inclusion criteria
Patients aged 16-40 presenting to our hospital with a first time anterior shoulder dislocation.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
Target: 50. As of Sep'07: 38.

Key exclusion criteria
1. Age less than 16 or more than 40
2. Patients unable to give informed consent
3. All vulnerable groups (mental illness, prisoners etc) and patients with an associated fracture requiring operative intervention

Date of first enrolment
01/11/2005

Date of final enrolment
01/11/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Orthopaedic Consultant
London
United Kingdom
SE18 4QH

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
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dhmail@doh.gsi.org.uk

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Queen Elizabeth Hospital NHS Trust (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