

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

Submission date

28/09/2007

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

28/09/2007

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

27/06/2013

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

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Contact details

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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

+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

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