Does aspiration of simple traumatic elbow effusions benefit the patients?

Submission date	Recruitment status	Prospectively registered
30/09/2004	No longer recruiting	[] Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2004	Completed	[_] Results
Last Edited	Condition category	Individual participant data
14/03/2014	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

Contact name Dr D Boon

Contact details

Accident and Emergency Dept Derriford Hospital Derriford Rd Plymouth United Kingdom PL6 8DH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0185131394

Study information

Scientific Title

Study objectives To ascertain whether aspiration of traumatic elbow effusions reduces pain, increases mobility and quality of life?

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: Traumatic elbow effusion

Interventions Randomly assigned to aspiration or not.

Intervention Type Other

Phase Not Specified

Primary outcome measure

Parameters of pain, mobility and quality of life will be assessed on presentation, after treatment, one day, one week and 3 months.

Secondary outcome measures Not provided at time of registration

Overall study start date

01/11/2003

Completion date 01/10/2007

Eligibility

Key inclusion criteria 150 patients with traumatic elbow effusions, or type 1/2 radial head fractures.

Participant type(s) Patient

Age group Not Specified

Sex Not Specified

Target number of participants 150

Key exclusion criteria Not provided at time of registration

Date of first enrolment 01/11/2003

Date of final enrolment 01/10/2007

Locations

Countries of recruitment England

United Kingdom

Study participating centre Accident and Emergency Dept Plymouth United Kingdom PL6 8DH

Sponsor information

Organisation Department of Health

Sponsor details Richmond House 79 Whitehall

London United Kingdom SW1A 2NL

Sponsor type Government

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

Funder(s)

Funder type Government

Funder Name Plymouth Hospitals 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