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Distal forearm torus fractures - do they need a splint?

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
19/10/2011	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
N0143185333

Study information

Scientific Title

Study objectives
To demonstrate that a torus fracture, treated with no splintage at all, is not significantly more painful than one treated with splintage and allows the child to start using the limb sooner.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Pilot 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: Fractures

Interventions
A pilot study recruiting for 1 year, using patients randomised into two groups after x-ray diagnosis. Pain, satisfaction and treatment evaluation will be conducted at 1 week using patient and carer responses. At 4 weeks, patient's carer will do a similar evaluation again.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Difference in pain levels at weeks 1 and 4 between the 2 groups
2. Time to return to normal use of affected limb with and without splintage
3. Patient and carer satisfaction level in the 2 groups.

Secondary outcome measures

Not provided at time of registration

Overall study start date
08/08/2006

Completion date
08/08/2007

Eligibility

Key inclusion criteria
All children under 17 presenting with a torus fracture of the distal end of the radius and or ulna.

Participant type(s)
Patient

Age group
Child

Upper age limit
17 Years

Sex
Not Specified

Target number of participants
30-50 patients to be recruited in total

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
08/08/2006

Date of final enrolment
08/08/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

A&E
Watford
United Kingdom
WD18 0HB

Sponsor information

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

Sponsor details
The Department of Health, 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
Hertfordshire Hospitals Research and Development Consortium (UK)

Funder Name
West Hertfordshire Hospitals NHS Trust

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