

Self Cast Removal at the Child's Home

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| Submission date 07/08/2008 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 13/08/2008 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 27/03/2013 | Condition category Injury, Occupational Diseases, Poisoning | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> 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

Protocol serial number
N/A

Study information

Scientific Title
A randomised controlled trial to assess the treatment of stable upper limb fractures in children, comparing traditional rigid casts with flexible casts suitable for home removal by the parent

Acronym
SCRATCH

Study objectives

An equivalence study of stable upper limb fractures in children to ascertain whether:

1. The use of a home-removable flexible cast is clinically equivalent to the rigid cast, in the management of stable upper limb fractures in children
2. The use of a home-removable flexible cast is more cost-effective than the hospital removal of a rigid cast, in the management of stable upper limb fractures in children
3. The parent and patient are satisfied with the use and home removal of the flexible cast

Ethics approval required

Old ethics approval format

Ethics approval(s)

Mid and South Buckinghamshire Research Ethics Committee. Date of approval: 12/03/2008 (ref: 08/H0607/20)

Study design

Pragmatic, individually randomised controlled equivalence study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Upper limb fractures in children

Interventions

Participants will be randomised to one of two basic treatment interventions:

1. Traditional plaster of Paris or fibreglass rigid cast with follow-up in the fracture clinic for removal
2. Home-removable flexible cast taken off at home by the parent/ carer. They will not be observed removing the cast but an appointment in fracture clinic will be available on request if required

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Clinical equivalence using the difference in Childhood Health Assessment Questionnaire score between pre-injury and one week post cast removal. Equivalence will be defined by a difference of less than 10%.

Key secondary outcome(s)

1. Clinical equivalence using the difference in Childhood Health Assessment Questionnaire score between pre-injury and 6 months post cast removal

2. Cost effectiveness of flexible casts over rigid casts
3. User satisfaction of flexible casts using a modified Paediatric Quality of Life Inventory (PedsQL) Healthcare Satisfaction Questionnaire to be completed at 1 week post cast removal

Completion date

13/03/2011

Eligibility

Key inclusion criteria

1. All children (both males and females) with stable upper limb fracture
2. Aged between 2 and 16 years
3. Presenting within 72 hours of sustaining the injury
4. Attending with a responsible adult

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

2 years

Upper age limit

16 years

Sex

All

Key exclusion criteria

1. Fracture other than simple torus, greenstick or stable epiphyseal fracture
2. Multi-limb trauma
3. In-patient
4. Suspicion of non-accidental injury
5. Previous surgery or significant injury to affected arm
6. Developmental delay
7. Failure to thrive
8. Pre-existing musculoskeletal disease affecting the upper limb
9. On medications that influence bone metabolism
10. Live outside the hospital catchment area or will find attending for follow-up difficult

Date of first enrolment

30/05/2008

Date of final enrolment

13/03/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Kadoorie Centre

Oxford

United Kingdom

OX3 9DU

Sponsor information

Organisation

Oxford Radcliffe Hospitals NHS Trust (UK)

ROR

<https://ror.org/03h2bh287>

Funder(s)

Funder type

Government

Funder Name

Oxford Radcliffe Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration