ISRCTN55089523 https://doi.org/10.1186/ISRCTN55089523

Self Cast Removal at the Child's Home

Submission date	Recruitment status	[ ] Prospectively registered
07/08/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
13/08/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/03/2013	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

Contact name
Prof Keith Willett

Contact details
Kadoorie Centre
John Radcliffe Hospital
Headington
Oxford
United Kingdom
OX3 9DU

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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%.

Secondary outcome measures
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

Overall study start date
30/05/2008

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

Age group
Child

Lower age limit
2 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
460

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
England

United Kingdom

Study participating centre
Kadoorie Centre
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
Oxford Radcliffe Hospitals NHS Trust (UK)

Sponsor details
John Racdliffe Hospital
Headington
Oxford
England
United Kingdom
OX3 9DU

Sponsor type

Hospital/treatment centre

Website
http://www.oxfordradcliffe.nhs.uk

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Government

Funder Name
Oxford Radcliffe 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