

# Self Cast Removal at the Child's Home

<b>Submission date</b> 07/08/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 13/08/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/03/2013	<b>Condition category</b> 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

### Contact name

Prof Keith Willett

### Contact details

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

## 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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	Participant information sheet				

