# 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