5 years after both-bone forearm fractures in children: bony remodeling and functional recovery.

Published: 06-05-2013
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To define the extent of bony remodeling and functional recovery, 5 years after a both-bone forearm fracture.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON41243

Source
ToetsingOnline

Brief title
-geen acroniem-

Condition

- Other condition

Synonym
Fracture of ulna and radius. Lekenterm: both-bone forearm fracture.

Health condition

Botaandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Indien onderzoeksgeld beschikbaar zal worden.

Intervention

Keyword: Children, Forearm fracture, Function, Remodeling

Outcome measures

Primary outcome

1. Funcional recovery, 5 years after a both-bone forearm fracture.

2. Bony remodeling: difference in radiological position of union 6 weeks

post-fracture and 5 years post-fracture.

Secondary outcome

1. Functional result in relation tot radiological position of union.

2. Pain and cosmetics, 5 years after a both-bone forearm fracture.

Study description

Background summary

Children posses the unique ability to correct a bony deformity. A malunion, is the result of a fracture. The extent of bony remodeling and funcional recovery of children after a both-bone forearm fracture mal-union (or antebrachial fracture) is unclear. Follow-up of the 'Fractura Antebrachii' study is an oppertunity to define the extent of bony remodeling and functional recovery, 5 years after a both-bone forearm fracture.

Study objective

To define the extent of bony remodeling and functional recovery, 5 years after a both-bone forearm fracture.

Study design

A prospective follow-up study of a randomised controlled trial.

Study burden and risks

Patients will have to visit the hospital once. They will fill in a two questionnaires, will undergo physical examination (wrist / forearm function, grip strength measurement) and two X-ray's.
A risk is the possible adverse effects of X-rays.

Contacts

Public
Reinier de Graaf Groep

Reinier de Graafweg 3-11
Delft 2625 AD
NL
Scientific
Reinier de Graaf Groep

Reinier de Graafweg 3-11
Delft 2625 AD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

1. Patients that were included in the Fractura Antebrachii study registered at the METC Zuidwest Holland with number 05-76.
2. Informed consent

Exclusion criteria

1. No inclusion in Fractura Antebrachii study registered at the METC with number 05-76.
2. No informed consent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-01-2014
Enrollment:	410
Type:	Actual

Ethics review

Approved WMO

Date:	06-05-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	22-05-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT00398242,NCT00314600,NCT00314587,NCT00397995,NCT00397852,NCT00398268
CCMO	NL41839.098.12