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

Published: 06-05-2013 Last updated: 26-04-2024

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

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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
Туре:	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