functional outcome of supracondylar fractures in children

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The aim of our study is to determine the functional outcomes in children after a supracondylar humerus fracture and comparing the outcomes of various treatment strategies.

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

Summary

ID

NL-OMON40218

Source ToetsingOnline

Brief title functional outcome of supracondylar fractures in children

Condition

• Fractures

Synonym elbow fracture, supracondylar fracture of the humerus

Research involving Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum **Source(s) of monetary or material Support:** afdelingsfonds Heelkunde-Traumatologie LUMC

Intervention

Keyword: children, fractures, functional outcome, supracondylar

Outcome measures

Primary outcome

- Objective elbow function
- Perceived (subjective) elbow function
- Sensibility in dermatomes of n. ulnaris, n. radialis and n. medianus
- Complications during and after treatment: infection, vascular injury, nerve

injury, non- or malunion, reoperation (other than removing k-wires), persistent

deformity on final radiographs.

Secondary outcome

none

Study description

Background summary

Supracondylar fractures of the humerus are among the most common fractures in children. The vast majority of these fractures occur from a fall on the outstretched hand with the elbow in full extension. Supracondylar humerusfracturen are classified according to Gartland: Gartland type I, non displaced fracture, Gartland type II; geanguleerde fracture with intact dorsal cortex, Gartland type III displaced fracture without cortical contact. Type I fractures are typically treated with a circular upper arm cast at 90 ° for 3 to 4 weeks. There is no consensus on treatment of Gartland type 2 fractures: these fractures can be treated with plaster or closed (or open if necessary) reduction and K-wire fixation followed by cast in 90°. The K-wires can be placed parallel or crossed. In the literature, there is discussion whether surgical treatment of type II fractures should be limited to type II-B fractures. Due to the lack of consensus there is variation in the treatment of type II fractures. Type III fractures are usually treated surgically. The guality and stability of the repositioning is of importance for the functional

outcome. The main complication of a supracondylar humerus fracture if not adequately treated is a cubitus varus with a permanent extension limitation. If this occurs only surgically repair is a treatment option. The results of this procedure are highly variable. Other functional outcomes after treatment of these fractures in children are not well known. In daily practice, a permanent functional limitation is often seen during outpatient follow-up after this type of fracture. At present it is not apparent from the literature what percentage of children suffer from permanent functional impairment and what is the degree of impairment.

Study objective

The aim of our study is to determine the functional outcomes in children after a supracondylar humerus fracture and comparing the outcomes of various treatment strategies.

Study design

In this observational study the long-term outcomes after treatment of supracondylar humeral fractures in children are evaluated in a retrospective cohort of patients who were treated in the LUMC, Juliana Kinderziekenhuis, Groene Hart Ziekenhuis and en MC Haaglanden in the period 2002-2011 . In this study, the outcomes (elbow function and complications) in the long term of the different treatments of supracondylar humeral fractures in children are studied. Following the data obtained an insight can be given into the treatment strategies and potential for further investigation can be determined.

Study burden and risks

The patients are invited for a one-time visit to the outpatient clinic. During the visit, the elbow function is tested and patients will fill out a questionnaire. The functional test is without risk and painless.

Contacts

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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

- supracondylar humeral fracture between 2002-2011
- at time of fracture between 4 and 16 years of age

- diagnosed and treated in LUMC, Juliana Kinderziekenhuis, Groene Hart Ziekenhuis or MC Haaglanden

Exclusion criteria

- no informed consent
- incompetent patiënt
- pathological fracture
- contralateral humeral fracture in patient history

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Treatment	

Recruitment

МП

INL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	07-07-2013
Enrollment:	600
Туре:	Actual

Ethics review

Approved WMO	
Date:	30-05-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO	
Date:	15-04-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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

ССМО

ID NL43694.058.13