

# Effectivity of splinting therapy for correction of anatomy in children with congenital hand deformities

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The objectives of this study are to gain more insight in the efficacy of splinting therapy for correction of the anatomy and answering the followig questions:1.What are the effects of conservative splinting therapy in children with congenital hand...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Musculoskeletal and connective tissue disorders congenital
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON30889

### Source

ToetsingOnline

### Brief title

Effectivity of splinting therapy

### Condition

- Musculoskeletal and connective tissue disorders congenital

### Synonym

congenital hand deformity, hand anomaly

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Johanna Kinderfonds;Stichting Kinderrevalidatiefonds Adriaanstichting

## Intervention

**Keyword:** congenital, function, hand deformities, Quality of life

## Outcome measures

### Primary outcome

Function (Mobility,Strength,Sensibility,Pain,Handfunction,Stability,Anatomy)

Esthetics

Qualityof life

Activity level

Participation level

### Secondary outcome

none

## Study description

### Background summary

Children, parents and doctors need to make important decisions in very young children about specific treatments such as splinting therapy and surgery. These therapies primarily aim at function and esthetics. It is of great importance for decision making to increase to insight into the effects of interventions. By improving our knowledge about longterm effects at all relevant levels, indication for therapy will be more clear. The medical team as well as the children and their parents need more insight into the implications of the choices that can be made.

As far as we know in this population, this intervention has not been investigated.

### Study objective

The objectives of this study are to gain more insight in the efficacy of splinting therapy for correction of the anatomy and answering the followig questions:

1.What are the effects of conservative splinting therapy in children with

congenital hand anomalies?

1. What are the effects of splinting therapy in children with congenital hand deformities?

2. What is the optimal duration of splinting therapy

## **Study design**

All children with congenital hand deformities that will receive conservative splinting therapy, will be included. Included children will be measured before therapy, and 3, 6, 12, 24, 36, 48 months after intervention. Measurements during and after intervention will be combined with appointments at the outpatient clinic. Children undergoing more therapies will be measured every 3 and 6 months after therapy.

Patients will have to fill out 3 questionnaires concerning function in daily life and development. The hand will be tested on several aspects, such as range of motion and strength. The questionnaires only need to be filled out at pre-therapy and after therapy at 12, 24 and 36, 48 months.

## **Intervention**

The intervention consists of a custommade thermoplastic splint made by a handtherapist and has to be worn during the night.

## **Study burden and risks**

Burden: measurement will be performed during normal visits at the hand therapy department for revision of the splint. Approximately 45 minutes extra time will be needed

Risk: There is no risk for the patients of participating in this study

## **Contacts**

### **Public**

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### **Scientific**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

### Inclusion criteria

splinting therapy, congenital hand deformity

### Exclusion criteria

age above 13 yrs

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2007
Enrollment:	60
Type:	Actual

## Ethics review

Approved WMO	
Date:	26-09-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## 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
CCMO	NL18101.078.07