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

Published: 26-09-2007
Last updated: 08-05-2024

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...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	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 an appointments at the outpatient clinic. Children undergoing more therapies will be measured every 3 and 6 months after therapy.
Patiënts 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 hantherapsits 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
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230

3015 CE
NL

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