Motor Abilities of Children with Clubfeet at Primary School Age.

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Objective: This study aims to investigate, whether children with clubfeet are facing difficulties in daily life on activity*s and participation, two domains of the ICF, comparing to their age-mates without clubfeet.

Ethical review	Not approved
Status	Will not start
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON34592

Source
ToetsingOnline

Brief title
MACCSA

Condition

- Musculoskeletal and connective tissue disorders congenital
- Musculoskeletal and connective tissue disorders congenital

Synonym
clubfeet, CTEV

Research involving
Human

Sponsors and support

Primary sponsor: Deventer Ziekenhuis
Source(s) of monetary or material Support: i.p. zijn er geen fondsen.

Intervention

Keyword: clubfeet, evidence, motor abilities, peadiatric physical therapy

Outcome measures

Primary outcome

-Walking distance (6MWT), (main parameter)

Secondary outcome

Jumping power,

-Sprint (10x 5 m sprint test),

-Motor performance in general (M-ABC2)

-Feeling of self-competence (CBSK-M).

-The functional status of the foot will be measured with the clubfoot

assessment protocol(CAP).

Study description

Background summary

Rationale: The idiopathic clubfoot is a congenital birth deformity with an incidence of 200 a year in the Netherlands. Treatment is in hands of a specialized orthopaedic surgeon, whose first aim is to correct the anatomical structures. In the past decennia different methods are used and these days conservative treatment seems to be the first option: A series of casts followed in 95 % by a tenotomy and thereafter a foot abduction brace for a period of four years, according the principles of dr. Ponseti, is at the moment world wide the first choice of treatment. Treatment starts soon after birth. According to the international classification of Function Disability and Health(ICF), correction of anatomical structures and function will be obtained in order to improve performance of daily activities and participation in sport without pain and stiffness. Most studies compare the outcome of the different treatment methods with correction of the anatomical structures and mobility as outcome parameter. Even if the anatomical correction is satisfactory, we still find some differences compared to children without clubfeet in the clinical presentation: a smaller foot, a thinner calf, reduced muscle strength and a

difference in mobility of the ankle and foot. Whether these differences in body structure and function also influence the child*s motor-activities and participation is not known. The study of Andriesse at al. is so far the only one, who investigated children with clubfeet on their motor performance. Andriesse also developed an instrument, the clubfoot assessment protocol (CAP), that measures not only the mobility, but also muscle function and activities. From practical experience we know, that children with clubfeet can face difficulties in daily life activities . What exactly these problems are and whether we can influence them with training is not yet known.

Study objective

Objective: This study aims to investigate, whether children with clubfeet are facing difficulties in daily life on activity*s and participation, two domains of the ICF, comparing to their age-mates without clubfeet.

Study design

Study design: This study is an observational matched pair control study. We compare the motor performance of primary school children with uni-or bilateral clubfeet with their age-mates without clubfeet by asking them to do some tests on different activities, as walking distance (6MWT), jumping force, sprint (10x 5 m sprint test) , motor performance in general (M-ABC2) and feeling of self-competence (CBSK-M). The functional status of the foot will be measured with the clubfoot assessment protocol(CAP).
The non-clubfoot children will be matched according to age, length, weight and gender.
For statistical analyses will be used the Fisher*s exact t-test , the Spearman correlation coëfficient and the Mann Whitney U-test.
Every child will be tested once.
The test per child will take approximately 2 hours.
The testers all have test experience.
There are two test locations. Rotterdam and Deventer for the convenience of the subjects.

Study burden and risks

All test performed are within the normal activity level of children of that age. There is no special burden to perform the tests and the risks associated with participation are none.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Children with congenital talipes equinovarus between 4-12 years old.
Bi-, or unilateral anatomical corrected clubfoot
Volunteered to take part and parents signed an informed consent form.
Their controls with same age, weight, height and gender.

Exclusion criteria

Children with CTEV and comorbidity, which could influence their motor ability, like arthrogryposis or Down syndrom.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	90
Type:	Anticipated

Ethics review

Not approved

Date:	20-09-2011
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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	NL32904.072.10