Function and participation of children with Ponseti treated clubfoot

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To investigate the differences in participation, motor abilities and function in more dynamic tasks between clubfoot patients with and without relapse and healthy controls.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON51193

Source
ToetsingOnline

Brief title
Function and Participation of clubfootpatients

Condition

- Other condition
- Musculoskeletal and connective tissue disorders congenital

Synonym
clubfoot, talipes equinovarus

Health condition

gezonde kinderen

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: SIA RAAK Publiek,Cooperatie Orthopedie Groot Eindhoven (Catharina Ziekenhuis/Máxima MC)/Fontys Paramedische Hogeschool

Intervention

Keyword: Clubfoot, Function, Gait analysis, Participation

Outcome measures

Primary outcome

Maximum plantar flexion at toe-off obtained with 3DGA during walking.

Secondary outcome

Mean PEM-CY, motor competence, M-ABC 2, and CAP scores of the different study groups. Furthermore, secondary study parameters are: kinematic, and kinetic parameters from the foot, ankle, knee and hip and muscle activity.

Study description

Background summary

Relapse after good initial correction of the clubfoot still occurs in clubfoot patients treated with the Ponseti method. Relapse of the clubfoot results in differences in foot function of the patients and could therefore also pose problems during daily life activities and participation. However, little is known about the difficulties in activity and participation of clubfoot patients and whether gait impairments can predict or illustrate those difficulties.

Study objective

To investigate the differences in participation, motor abilities and function in more dynamic tasks between clubfoot patients with and without relapse and healthy controls.

Study design

Observational study with two measurement sessions where three-dimensional gait

analysis, questionnaire on perceived motor competence, the movement assessment battery for children 2 (M-ABC 2) and clubfoot assessment protocol (CAP) are performed. Furthermore, parents are asked to fill in a digital questionnaire which consists of the Participation and Environment Measure for Children and Youth (PEM-CY) and M-ABC 2 checklist. Clubfoot relapse patients are measured pre- and post-treatment.

Study burden and risks

Children and parents will not undergo any risks or hindrance during the measurements, as the clinical measurements are like the test performed during their regular treatments/ consults. However, the participant and parents will spend three hours, divided over two separate day for the measurements.

Contacts

Public
Maxima Medisch Centrum

Dominee Theodor Fliednerstraat 1
Eindhoven 5631 BM
NL
Scientific
Maxima Medisch Centrum

Dominee Theodor Fliednerstraat 1
Eindhoven 5631 BM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Both controls and (relapse) clubfoot patients who:
- Are 5 - 9 years old
- Have parents with sufficient command of the Dutch language

Clubfoot patients who:
- Have idiopathic clubfoot
- Are uni- or bilaterally affected
- Have been primarily treated with the Ponseti method

Relapse clubfoot patients:
- Reoccurrence of one or more clubfoot aspects that requires additional treatment as judged by the expert opinion of the treating orthopaedic surgeon.
Additional treatment according to regular care includes:
• Non-invasive treatment with physiotherapy,
• Surgical treatment, consisting of a period of bracing followed by one of the following surgical procedures: a tibialis anterior tendon transfer (TATT), anterior distal tibial epiphysiodesis (8-plate), or a combination of both procedures.

Exclusion criteria

Both controls and (relapse) clubfoot patients who:
- Are unable to follow the instructions
- Have obesity, based on their age-category and gender
- Have an underlying syndrome
- Have a neurological disease
Controls who:
- Have problems of the lower extremity
(e.g., hip dysplasia/ broken leg <1year prior to participation)

All clubfoot patients who:
• Did not have their primary treatment in the Netherlands
• Previously received additional surgical treatment (with exception of re-Achilles tendon tenotomy) for a relapse of their clubfoot.

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:	Recruiting
Start date (anticipated):	03-12-2021
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	16-04-2021
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	19-11-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL76757.015.21