Function and participation of children with Ponseti treated clubfoot

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It is hypothesized that (relapse) clubfoot patients show reduction in participation, lower motor ability and larger deficits in movement patterns during dynamic tasks compared to typically developing children.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25499

Bron
NTR

Verkorte titel
FunPartClub

Aandoening

clubfoot / relapse clubfoot

Ondersteuning

Primaire sponsor: Raad van bestuur Máxima MC
Overige ondersteuning: SIA RAAK PRO

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
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. It is hypothesized that (relapse) clubfoot patients show reduction in participation, lower motor ability and larger deficits in movement patterns during dynamic tasks compared to typically developing children.
Objective:
To investigate the differences in participation, activity and function based on dynamic tasks between clubfoot patients with and without relapse and healthy controls. Study design:
Observational study with two measurements of approximately 90 and 60 minutes. In the first measurement, three-dimensional gait analysis (3DGA) is done and the child is asked to qive their ooinion about several activities usinq the questionnaire on perceived motor competence. In the second measurement, the movement assessment battery for children 2 (M-ABC 2) and clubfoot assessment protocol (CAP) are performed. Furthermore, parents are asked to fill (approximately 30 min) in the M-ABC 2 checklist and the particioation and environment measure children and vouth (PEM-CY) online. The relapse group will undergo a similar assessment after treatment.
Study population:
30 healthy children, 30 clubfoot patients without a relapse and 30 clubfoot patients with a relapse between the age of 5-9.
Intervention: NA
Main study parameters/endpoints: The main study parameters for participation and motor abilities are the mean PEM-CY and M-ABC 2 scores of the different study groups. The main study parameters for the function are the kinetic and kinematic parameters with special focus on the Oxford foot model (OFM) angles.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
The first measurement where the 3DGA is done, will be performed by a qualified researcher. It is expected that patients will not undergo any risks or hindrance during this measurement, but parents and children will spend approximately 90 minutes for the first measurement session, 60 minutes for the second measurement session and 30 minutes for the online questionnaire. Considering the new environment and circumstances of the measurement, children could get tired after the measurement. Furthermore, the second measurement session will not be planned on the same day as the first measurement session, and therefore the participant and parent will have to come back at another time. Also, participation in the study will not automatically result in advantage for the child. To gather normative data for comparison with data from the patient population, it is necessary to include healthy children in this study because the not affected side in unilaterally affected clubfoot patients cannot be

considered normal.

Doel van het onderzoek

It is hypothesized that (relapse) clubfoot patients show reduction in participation, lower motor ability and larger deficits in movement patterns during dynamic tasks compared to typically developing children.

Onderzoeksopzet

The first measurement session will consist of 3DGA. The second measurement session will be max 4 weeks after session 1. In the second sesson assessment of the CAP and M-ABC 2 test will be performed by an experienced physiotherapist. The questionnaires that are used in this study are the PEM-CY and M-ABC 2 checklist for parents and the questionnaire on perceived motor competence for children.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Both controls and (relapse) clubfoot patients who:
- Are 5 - 9 years old

- Have parents with sufficient command of the Dutch language

(Relapse) 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Both controls and (relapse) clubfoot patients who:
- Are unable to follow the instructions
- Have obesity
- 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-08-2021
Aantal proefpersonen:	90
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	08-07-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9593
Ander register	METC MMC : W21.015

Resultaten