Feasibility study of an orthosis for treatment of a Clubfoot

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Interventional

Summary

ID

NL-OMON52544

Source
ToetsingOnline

Brief title
Orthosis for treatment of a clubfoot

Condition

- Musculoskeletal and connective tissue disorders congenital

Synonym
clubfoot

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: brace, clubfoot, dynamic, Ponseti

Outcome measures

Primary outcome

The primary outcomes are amount of correction defined by the Dimeglio and

Pirani score, time needed for treatment and malfunctioning of the brace.

Secondary outcome

The secondary outcome measure is physical complications of the treatment,

caused by the brace.

Study description

Background summary

An idiopathic clubfoot - or congenital talipes equinovarus - is a congenital deformation of the foot. Approximately 1 per 1000 children are born with a unilateral or bilateral clubfoot, which makes it one of the most common congenital deformities. In the Netherlands every year approximately 190 children are born with a clubfoot (Besselaar et al. 2018). Its incidence is higher in boys than in girls and in about half of the cases it is bilateral (both feet are affected). Sex and laterality do not influence the severity of the deformity (Zionts et al., 2017). Clubfeet are commonly treated with serial casting, named the Ponseti method (Ponseti, 2008; Ponseti et al., 1963). The Ponseti method is worldwide accepted as the golden standard for the treatment of a clubfoot (Hennessey, 2012). In this method, the clubfoot is weekly manipulated and fixated in a slightly more corrected position using a plaster cast. The cast is typically changed every week for approximately 4 to 6 weeks. In many cases a percutaneous Achilles tenotomy is done after casting for the final clubfoot correction. An abduction brace is worn for several years to prevent any relapse (Dobbs et al., 2004).

Although the Ponseti method is highly effective in the treatment of clubfoot, there are many clues indicating that the Ponseti method is in need of a correction. The plaster cast of the Ponseti method prevents bathing, gets in the way with diaper changes, interferes with cuddling. Additionally, the cast appears to cool the child*s feet (Giesberts et al., 2018) and to provoke

judgement from people suggesting physical abuse. Its position-controlled approach is likely to be inefficient. Experiments, in which the cast is changed more frequently in an attempt to minimize the treatment duration (e.g. Harnett, Freeman, Harrison, Brown, & Beckles, 2011) showed the same positive result without any negative consequence. In our experience these issues are unknown to most treating physicians and easily dismissed. Several studies have indicated the need for medical professionals to acknowledge that the Ponseti method causes increased stress for the families (Malagelada et al., 2016; Nogueira et al., 2013). For some caregivers these issues are real and require a solution.

Our hypothesis is that the clubfoot treatment can be improved by the use of a dynamic clubfoot brace that is based on a force-controlled approach instead of a position-controlled approach, because it will accelerate the correction process, making it a more efficient treatment option and making the treatment more user-friendly. Moreover, the number of hospital visits will be reduced from at least 7 to 2.

Study objective

Primary Objective
The primary objective of this study is to examine the feasibility of using the clubfoot brace. This will be done by recording the effect of the brace on the clubfoot deformity by determining the improvement of the Dimeglio and Pirani score progress during three stages:
• First stage: at the start and after two hours
• Second stage: at the start and after one week
• Third stage: at the start and end of the treatment (before an Achilles Tenotomy is performed)
The time for full correction is also part of the feasibility, because we aim at an accelerated correction process.
In addition, the caregivers will fill out a log to record when they remove the clubfoot brace, and which problems they experience with the brace during use and while taking it on and off. Other experiences with the clubfoot brace such as malfunction or a part breaking while using the brace are documented in the log during the study period as well.

Secondary Objective
The secondary objective of this study is to evaluate physical complications the baby and the caregivers experience using the brace. The caregivers will fill out a log to record, which physical problems the clubfoot brace cause such as skin problems or pain.

Study design

Observational pilot study.

Duration:
From 19 September 2022 to 19 April 2024

Intervention

A brace was realized that can treat a clubfoot and can be removed temporarily for diaper change or a bath. The force applied on the foot by the brace should be enough to correct the deformations of the foot, targeting all four aspects of deformity similarly to how it is done with the Ponseti method.
The brace will be fixed to the leg via two adaptable straps (to account for different sizes and growth), one around the thigh and one below the knee. The brace is in contact with the foot and apply force only in two locations: the Talar Neck (TN) and the First Metatarsal (FM), the same locations used in the Ponseti method. Two polymer spiral structures with spring-like behaviour will generate the force on the TN and FM and the lower leg. Each spiral spring initial position matches the foot in the normal, corrected position. Therefore, when a spiral spring is stretched to fit the deformed foot, it will generate forces to return to the initial position. The correction will be done in two stages, again according to the Ponseti protocol. The first stage will use spiral spring 1 to correct the cavus deformity. The second stage will use spiral spring 2 that corrects the adductus and varus deformity.

Study burden and risks

The burden for patients involves wearing the brace. Furthermore patients have to visit the hospital twice a week for check-up. During a three week intervention period a log should be kept daily to monitor the use of the brace. The major risk while using the brace is that the clubfoot is not corrected due to the change in position of the brace on the foot. The major benefit may be the improvement of the clubfoot treatment compared with the Ponseti method in terms of duration of the treatment, limited number of visits to the hospital, increased comfort for the baby and the parents and the absence of the parents being accused of child abuse.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Newborns

Inclusion criteria

• A moderate to severe clubfoot deformity according to the Dimeglio scoring system (grade II or III)
• Start of the Ponseti treatment within 2 weeks after birth
• No other deformities of the foot or leg
• Written informed consent

Exclusion criteria

• previously treated by the Ponseti method
• characterised by grade IV according to the Dimeglio scoring system
• have other health complications, because they could interfere with the results of the brace

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	brace
Registration:	No

Ethics review

Approved WMO Date:	19-12-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-10-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL70525.042.19