Functional outcome of clubfeet using a new type of brace.

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20366

Bron
NTR

Verkorte titel
To Advance is to Move

Aandoening

clubfeet, clubfoot, dynamic brace, Ponseti.
klompvoeten, dynamische brace

Ondersteuning

Primaire sponsor: AGP van Ruiten/ dr. R.H.G.P. van Erve
Overige ondersteuning: fonds=verrichter=sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study endpoint is at age 4 years. This will be the follow-up for this research.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
A club foot is a congenital deformity with a multifactor etiology. It is a common anomaly affecting approximately 1-2 per 1000 births. The treatment is surgical or non-surgical. In literature the early results of surgical management of clubfeet is promising. However, the long-term results show inferior outcome with a painful and stiff foot. Serial casting and manipulation according to the Ponseti method6 show good short-term and long-term results.

An important part of the treatment consists of a foot abduction orthosis (FAO). Most surgeons use a static brace, for example a Dennis-Brown brace. Recurrence of clubfeet are in part contributed to the lack of compliance in using this orthosis.

In our practice we devised a fully dynamic brace (Dynko brace). Our believe is that the dynamic component which allows rotation and walking/kicking movements will increase the comfort in wearing and by this increase compliance. Secondary we believe this will have a positive influence on the neuromotor development of the child. Thirdly we assume that the dynamic loading of soft tissue structures that constitute the limits of range of motion in abduction, eversion and dorsal flexion will lead to a more natural growth balance in these limiting factors of range of motion.

Objective:
The primary objective is to obtain a plantigrade foot which will be shoed with conventional shoes.

The secondary objective will be the prevention of recurrences. Another objective will be to ascertain if the neuromotor development will be more and faster with the use of the studied brace. And if there will be less atrofie of the muscles of the lower leg.

Study design:
This study will be a open-label trail.

Study population:
The study population consists of all patients with clubfeet referred to the Deventer Ziekenhuis.

Intervention (if applicable):
All clubfeet are treated with serial casting according to Ponseti. After correction of the foot, this correction is maintained using a fully dynamic brace (Dynko-brace).

Main study parameters/endpoints:
The main study endpoint is at age 4 years. This will be the follow-up for this research.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
At day 1-10 after birth clubfeet will be recognized. At this primary consult, age at start of treatment, gender, co-morbidity, laterality of the clubfoot, family history will be registered. The Pirani score will be taken of the clubfeet. This is a reliable, quick, and easy to use scoring system with substantial inter-observer reliability. The measurement of this score is normal practice in treating clubfeet.
After initiating treatment the foot will be corrected using approximately 5-6 plaster changes. With every change the Pirani score will be obtained. The final amount of changes will also be recorded. At the twelfth week the need for an Achilles tenotomy will be decided. In literature over 90% will need this tenotomy. Also the Pirani score will be taken. To measure the functional outcome and the neuromotor development we use the Clubfoot Assessment Protocol (CAP). This scoring system uses clinical data to label the feet in categories. It is a reliable and validated method. The purpose of the CAP is to provide an overall profile of the clubfoot child's functional status within the domains of body function/structure and activity on single assessment occasions and over time.

At six months the Pirani score and the CAP will be taken.

At 12 months the Pirani score, CAP, and also the measurement of the greatest circumference of the lower leg (around the calf muscle) and the foot length will be recorded This to determine the amount of atrofie of the lower leg. We will compare this with the childs contralateral leg (in unilateral situations).

At 18 months the Pirani score and the CAP will be taken.

At 24 months the Pirani score, CAP, and the measurement of the greatest circumference of the lower leg (around the calf muscle) and the foot length will be recorded.

The last mentioned parameters will also be taken at the third and fourth year.

The CAP and the measurement of the lower leg will account for some extra time, however this will take place at regular visits to the physician/fysiotherapist.

It is our believe that the patient will benefit from the use of a fully dynamic device in that it will be more comfortable. It is our hope that the ability of movement in the brace will increase compliance. Furthermore, it is imperative that children are used in this research, because the condition of clubfeet is a congenital disorder.

Doel van het onderzoek

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comfort in wearing and by this increase compliance. Secondary we believe this will have a positive influence on the neuromotor development of the child. Thirdly we assume that the dynamic loading of soft tissue structures that constitute the limits of range of motion in abduction, eversion and dorsal flexion will lead to a more natural growth balance in these limiting factors of range of motion.

Onderzoeksopzet

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Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All patients with clubfeet born in the referral area of the Deventer Ziekenhuis are selected for this study. There is a intention to treat. That means all patients will undergo at start the same treatment. That is, if conservative treatment is possible.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

As mentioned above, all patients with clubfeet will be included. However, patients who do not respond to conservative treatment with manipulation and plaster correction, and therefore need surgery will be identified.
Also, a subgroup will be made with patients with a neuromuscular condition or a syndrome. Patients where treatment is not started within 10 days after birth will be excluded. Patients who will not take part of this study will also be grouped and followed throughout this study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	06-01-2009
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-09-2009
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	NL1911
NTR-old	NTR2028
Ander register	ABR : 29620
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A