Quality of Life assessment of children with clubfeet using a new type of brace.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25230

Source
Nationaal Trial Register

Brief title
Dynko brace; quality of life

Health condition

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

Sponsors and support

Primary sponsor: AGP van Ruiten/ dr. R.H.G.P. van Erve
Source(s) of monetary or material Support: fonds=verrichter=sponsor

Intervention

Outcome measures

Primary outcome

The main study endpoint is at age 18 months. This will be the follow-up for this research.

Secondary outcome

Secondary endpoint is failure of maintaining correction using the Dynko brace. Non-compliance will also be a secondary endpoint.

Study description

Background summary

Rationale:
A club foot is a congenital deformity with a multifactorial 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 shows 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 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.

Objective:
The primary objective of this study will be to ascertain the quality of life of the children using the fully dynamic brace as part of the conservative treatment of their clubfeet. As a secondary objective we will registrar the compliance in wearing the device.

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 18 months. This will be the follow-up for this research.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
The quality of life will be scored using the Infant Toddler Quality of Life Questionnaire (ITQOL). The questionnaire will be used first at 3 months. This will be a base-line, as a brace is not worn yet. Second time will be at 6 months, after which the brace will be used only at night time and sleeping periods. The third time will be at one year of age. The fourth time will be at 18 months, when most children will be able to walk. This questionnaire is extra to the normal treatment of clubfeet.

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.

Study objective

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.

Study design

The questionnaire will be used first after the tenotomy. This will be a base-line, as a brace is not worn yet. Second time will be at 6 months, after which the brace will be used only at night time and sleeping periods. The third time will be at one year of age. The fourth time will be at 18 months, when most children will be able to walk.

The secondary objective will hopefully be answered by integrating the FAO with a system that enables us to measure duration of use. The system will show how long the Dynko has been worn. The readings will be collected during the same control appointments, 3 months, 6 months, 12 months and 18 months.

Intervention

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). The quality of life will be scored using the Infant Toddler Quality of Life Questionnaire (ITQOL). The questionnaire will be used first at 3 months. This will be a base-line, as a brace is not worn yet. Second time will be at 6 months, after which the brace will be used only at night time and sleeping periods. The third time will be at one year of age. The fourth time will be at 18 months, when most children will be able to walk. This questionnaire is extra to the normal treatment of clubfeet.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

As mentioned above, all patients with clubfeet will be included.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-01-2009
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-09-2009
Application type:	First submission

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
NTR-new	NL1910
NTR-old	NTR2027
Other	ABR : 29539
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A