Splint: The efficacy of orthotic management in rest in children with cerebral palsy, a randomised controlled trial.

No registrations found.

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

Summary

ID

NL-OMON27440

Source
Nationaal Trial Register

Brief title
Splint

Health condition

Cerebral palsy, cerebrale parese, children, kinderen, ankle range of motion deficits, enkel range of motion beperking, muscle shortening, spierverkorting

Sponsors and support

Primary sponsor: VU University Medical Center
Department of Rehabilitation Medicine
Source(s) of monetary or material Support: Dr. W.M. Phelps Stichting voor Spastici and Ultraflex Systems inc.

Intervention

Outcome measures

Primary outcome

Ankle range of motion, measured with a dynamometer.

Secondary outcome

1. Maximal knee extension in stance during barefoot gait;

2. Maximal knee extension in stance during gait with shoes and AFOs;

3. Ankle dorsiflexion in mid stance during barefoot gait;

4. The level of mobility;

5. Morphological parameters.

Study description

Background summary

Objectives:

1. To evaluate the efficacy of knee-ankle-foot orthoses (worn in rest) and to evaluate the differences in efficacy between dynamic and static knee-ankle-foot orthoses in preventing a decrease of range of motion to ankle dorsiflexion in children with cerebral palsy (Clinical part);

2. To evaluate the effect of in rest-worn knee-ankle-foot orthosis on muscle morphology in children with cerebral palsy (Morphological part).

Participants:
Children with spastic cerebral palsy (aged 4-12 years) who have been successfully treated in the past for a decreased range of motion (to dorsiflexion) in the ankle.

Setting:
Two departments of rehabilitation medicine in the Netherlands (VU University medical center, Amsterdam and Groot Klimmendaal, Arnhem). Data of a study performed at the department of Neurology of the Washington University, St Louis, USA will be combined with this study and

then analysed together. Morphological data will be collected in the Netherlands only.

Design:
A single blind randomised controlled trial will be performed. Three groups will be investigated. Two groups will be treated for muscle shortening (prevention of recurrence of decrease of range of motion) with static or dynamic knee-ankle-foot-orthoses for 1 year and one group will be included as a control group receiving usual care. Measurements will be performed at baseline and at 3, 6, 9 and 12 months after treatment allocation.

Intervention:
One group will be treated with a custom made static knee-ankle-foot orthosis with a fixed ankle angle and one group will be treated with a custom made dynamic knee-ankle-foot orthosis using an ultraflex„¥ ankle power unit (variable ankle angle). Both knee-ankle-foot orthoses have a fixed 0o knee extension. The control group will receive usual care only. All groups continue with their usual therapies.

Main outcome measures:

1. Clinical part: The primary outcome measure will be ankle range of motion to dorsiflexion. The secondary outcome measures will be i) maximal knee extension in stance during gait, ii) ankle dorsiflexion in mid stance during gait and iii) the gross motor function measure;

2. Morphological part: The outcome measures will be morphological parameters like achilles tendon length, muscle belly length, muscle fibre length, muscle physiological cross sectional area length and fibre pennation angle.

Study objective

It is hypothesised that children who have been treated with a knee-ankle-foot orthosis show an increase or smaller decrease of range of motion to dorsiflexion in time compared to the children in the control group. In addition, it is expected that children wearing the static knee-ankle-foot orthosis show less increase or more decrease in ankle range of motion to dorsiflexion compared to children wearing the dynamic knee-ankle-foot orthosis. Consequentially, it is expected that children wearing the knee-ankle-foot orthosis show a smaller unfavorable change in or improved knee and ankle angles during gait compared to children in the control group. This is also expected in children wearing the dynamic knee-ankle-foot orthosis compared to the static knee-ankle-foot orthosis.
Lastly, it is expected that children who have been treated with a knee-ankle-foot orthosis show an increase or smaller decline of level of mobility compared to children in the control group. This is also expected in children wearing the dynamic knee-ankle-foot orthosis compared to the static knee-ankle-foot orthosis.

Morphological part: it is hypothesised that the tendon of the MTC and the muscle fibres and PCSA increase in length due to sustained strain. These possible morphological differences are related to the passive ankle moment – ankle angle relationship and to the efficacy of the treatment.

Study design

All outcome measures: baseline, 3 months, 6 months, 9 months, 12 months.

Methods:

1. Ankle ROM: dynamometer;

2. Ankle dorsiflexion and knee flexion during gait: videoanalysis;

3. Level of mobility.

Intervention

1. Group 1: Static knee-ankle-foot orthosis;

2. Group 2: Dynamic knee-ankle-foot orthosis (with ultraflex power unit);

3. Control group: No orthosis.

One group will be treated with a custom made static knee-ankle-foot orthosis with a fixed ankle angle and one group will be treated with a custom made dynamic knee-ankle-foot orthosis using an ultraflex„¥ ankle power unit (variable ankle angle). Both knee-ankle-foot orthoses have a fixed 0o knee extension. Treatment lasts one year. The control group will receive usual care only. All groups continue with their usual therapies.

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Eligibility criteria

Inclusion criteria

Children are included if:

1. They have a clinical diagnosis of unilateral or bilateral spastic CP;

2. They have an age between 4-12 years old;

3. They have a range of motion in the ankle of 0º dorsal flexion or more with an extended knee, tested by the clinician with reasonable manual force;

4. They are able to walk with or without aids (GMFCS class 1-3);

5. They have been treated for a decreased range of motion in the ankle by:

A. AND/OR serial casting at least 3 months ago;

B. AND/OR botulinum toxin A injections in the Gastrocnemius and / or Soleus muscle at least 6 month ago;

C. AND/OR Orthotic management in rest with a Knee-Ankle-Foot-Orthosis to prevent the decrease of range of motion in the ankle before the start of the study;

D. They live in a stable social family situation.

Exclusion criteria

Children are excluded if:

1. Surgery of the Gastrocnemius and/or Soleus muscle has been performed in the past;

2. A Selective Dorsal Rhizotomy has been performed in the past;

3. There is administration of treatment of Intra Thecal Baclofen therapy;

4. They had botulinum toxin A treatment less than 6 month ago in the lower extremity;

5. The cannot extend their knees to 0o;

6. They have behavioural problems or sleeping problems;

7. The child is institutionalized;

8. There is co-morbidity interfering with mobility;

9. Parents/guardians and/or child do not understand the Dutch or English language well enough to take part in this project.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2009
Enrollment:	66
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-11-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36506
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1974
NTR-old	NTR2091
CCMO	NL28986.029.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36506

Study results

Summary results
N/A