The efficacy of night splinting in children with cerebral palsy, a randomised controlled trial

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1) To evaluate the efficacy of knee-ankle-foot orthoses (worn by night) in preventing a decrease of range of motion to ankle dorsiflexion in children with cerebral palsy (Clinical part). 2) To evaluate the effect of night-worn knee-ankle-foot...

Ethical review	Approved WMO
Status	Completed
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON36506

Source
ToetsingOnline

Brief title
Splint

Condition

- Movement disorders (incl parkinsonism)

Synonym
spastic children, spastic diplegia and hemiplegia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Dr. W.M. Phelps Stichting voor Spastici,Ultraflex Systems inc.

Intervention

Keyword: cerebral palsy, children, knee-ankle-foot-orthosis, range of motion

Outcome measures

Primary outcome

The primary outcome measure will be ankle range of motion to dorsiflexion.

Secondary outcome

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.

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 description

Background summary

Children with cerebral palsy often have an impaired range of motion of the ankle. The decreased range of motion develops over time. Although the underlying mechanism behind the decreasing range of motion is not clear, it is supposed that impaired range of motion is caused by an insufficient length of the m. gastrocnemius. Treatments for impaired ankle range of motion seems to be effective on the short term, but not on the long term. Therefore, prevention for a decrease of range of motion is necesarry.

Study objective

1) To evaluate the efficacy of knee-ankle-foot orthoses (worn by night) in preventing a decrease of range of motion to ankle dorsiflexion in children with cerebral palsy (Clinical part). 2) To evaluate the effect of night-worn knee-ankle-foot orthosis on muscle morphology in children with cerebral palsy (Morphological part).

Study design

A single blind randomised controlled trial will be performed. Two groups will be investigated. One group will be treated for muscle shortening (prevention of recurrence of decrease of range of motion) a dynamic knee-ankle-foot orthosis for 1 year and one group will be included as a control group receiving usual care. Children needing treatment for reduced ankle dorsiflexion will be treated with botuline toxine A injections, serial casting and/or KAFOs during the first three months of the study. Randomisation will be performed after three months. Measurements will be performed at baseline and after 3, 6, 9 and 12 months.

Intervention

One group will be treated with a custom made dynamic knee-ankle-foot orthosis using an ultraflex ankle power unit (variable ankle angle). The knee-ankle-foot orthoses has a fixed 0 degrees knee extension. The control group will receive usual care only. All groups continue with their usual therapies.

Study burden and risks

It is hypothesised that the treatment will prevent a decrease of range of motion of the ankle in children with cerebral palsy. Besides, the results of this study can improve the treatment of these children as this study will give more insight in the underlying mechanisms of the children's decreasing ankle range of motion and the effects of the treatment. The risks of this study are comparable to normal treatment of children with cerebral palsy. We believe the benefits clearly outweigh the risks or burdens for the subjects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

They have a clinical diagnosis of unilateral or bilateral spastic CP
They have an age between 4-12 years old
They have a range of motion in the ankle of 0º plantar flexion or less with an extended knee, tested by a clinician with a manual force.
They are able to walk with or without aids (GMFCS class 1-3).
They have a range of motion in the ankle less than 5º with an extended knee, tested by the clinician with reasonable manual force and will be treated with:
* Botulinum toxin A injections in the m. Gastrocnemius
* AND/OR serial casting
* AND/OR orthotic management in rest with a Knee-Ankle-Foot-Orthosis
o OR they have a range of motion in the ankle less than 20 degrees and more than 0 degrees dorsiflexion and they have been treated for a decreased range of motion (defined as less than 5 degrees dorsiflexion) in the ankle in the past by:
* Botulinum toxin A injections in the m. Gastrocnemius (at least 6 months ago)
* AND/OR serial casting (at least 3 months ago)
* AND/OR orthotic management in rest with a Knee-Ankle-Foot-Orthosis
They live in a stable social family situation.

Exclusion criteria

Surgery of the Gastrocnemius and/or Soleus muscle has been performed in the past.
A Selective Dorsal Rhizotomy has been performed in the past
There is administration of treatment of Intra Thecal Baclofen therapy
The cannot extend their knees fully.
They have behavioural problems or sleeping problems.
The child is institutionalized.

There is co-morbidity interfering with mobility.
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)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	16-03-2010
Enrollment:	24
Type:	Actual

Medical products/devices used

Generic name:	Ultraflex ankle power unit
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-10-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-07-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27440
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL28986.029.09
OMON	NL-OMON27440