Contractures and dynamic splinting in Duchenne Muscular Dystrophy: Effects on gait economy.

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This study will consist of two parts. In the primary observational part we will assess kinematic and kinetic walking patterns in Duchenne Muscular Dystrophy. Goal is to asses the correlation between progressive contractures and gait patterns. This...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neurological disorders congenital
Study type	Interventional

Summary

ID

NL-OMON33285

Source
ToetsingOnline

Brief title
Gait economy and splinting in DMD

Condition

- Neurological disorders congenital
- Musculoskeletal and connective tissue disorders congenital
- Neuromuscular disorders

Synonym
Duchenne Muscular Dystrophy (DMD), muscular dystrophy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Contractures, Duchenne Muscular Dystrophy, Gait analysis, Orthosis

Outcome measures

Primary outcome

1. Observational study

Primary outcome is to describe the correlation between contractures of the ankle and gait. Children will walk on their toes to create an external extension moment on the knee and thus stability, leading to ankle contractures. Ankle contractures will hypothetically cause a greater plantar flexion moment at the end of the lengthening phase, creating a push-off at heel rise. The results will be compared to the findings of Gaudreault et al. (2009).

2. Intervention study

In the intervention study, gait analysis is repeated in exactly the same way, only this time with AFO*s on both sides.

Primary outcome: Change of the functional measures in walking with and without the dynamic AFO, such as gait velocity, timed motor performances and fatigue with non-parametric statistics. Expected is that with the AFO*s children will improve the 6 minute walking test (6MWT) with 10%.

Secondary outcome

1. Observational study

We suspect to find the following correlations:

• A positive correlation of PROM of the ankle and foot clearance during swing.

A contracture of the Achilles tendon will complicate foot clearance.

• A negative correlation of PROM of the ankle and passive plantar flexion

moment at the end of the lengthening phase. A contracture of the Achilles

tendon will store energy while tensed, causing a passive plantar flexion moment

at the end of the lengthening phase.

2. Intervention study

Secondary outcomes:

• Change of clearance of the foot, circumduction and pelvic tilt during swing

phase with use of the dynamic ankle-foot orthosis versus walking without

braces. Expected is to find a positive effect of the AFO*s.

• Change of stride length, cadence and gait velocity using the AFO*s. Expected

is to find a positive effect of the AFO*s.

• Positive correlation of PROM and the strength of the spring of the dynamic

AFO needed to achieve clearance in swing phase

Study description

Background summary

In 1981, Sutherland et al. described gait patterns in Duchenne Muscular Dystrophy (=DMD) patients. They found that lumbar lordosis is the earliest postural change observed in gait and that this was probably a compensation to keep the force line behind the hip after weakness of the m. gluteus maximus. They also described the necessity of equinus posture for knee stability. This is a provoking pose for shortening of the Achilles tendon.
Armand et al (2005) compared gait of 2 SMA patients with 2 DMD and concluded that DMD children use hip and circumduction of the leg to move body forward.

Furthermore, maintenance of stance seemed to be achieved through equinus and lordosis. The main difference observed in gait was less pelvic instability in DMD children, despite their weak abductor muscle strength. They proposed that this could be caused by contracture of the tibio-iliac tract or the higher abductor moment because of toe-standing. This leads to the assumption that contractures can also have positive effects in gait instead of only deteriorating the process of wheelchair dependence.

An evaluation of plantar flexion contractures in DMD was performed by Gaudreault et al. in 2009. They measured passive ankle plantar flexion moments by hand held dynamometer and net moments by gait analysis in 11 DMD boys and 14 controls and concluded that the relative passive moment contribution to the net plantar flexion moments was higher in boys with DMD compared to controls. The higher rigidity coefficient in contractures seems to lead to energy storage in the ankle and a higher plantar flexion moment in the end of the lengthening phase in gait.
The fact that ankle contractures can contribute positively to gait is supported by a study in stroke patients (Lamontagne et al. in 2000), but is also seen in healthy runners: Scholz et al. (2008) found that in healthy runners, the amount of stored energy in Achilles tendon increases as moment arm gets smaller, leading to better running economics.
In Duchenne Muscular Dystrophy due to Achilles tendon contractures the moment arm gets smaller, thus hypothetically leading to better gait economics. In other words ankle contractures can be beneficial as an energy storing mechanism in the pre-swing phase of the walking cycle and release of this energy in the toe-off (foot clearance of the floor) in the initial swing phase.

In the management of DMD much emphasis is put on controlling contractures. However, contractures of the Achilles tendon could be a very useful adaptation of the body. A frequently seen problem however with these contractures is stumbling in swing phase by balance problems and the need for more pelvic tilt for moving forward. This can be a cause of fatigue. Thus there seems to be a precarious balance between walking ability and extent of contractures, but also between standing ability and extent of contractures. For walking ankle contractures causing equinus seem to be preferable as an energy storing mechanism and as a good lining for the lumbar lordosis, while for standing and the swing phase during walking a minimal equinus is preferable.

There are dynamic orthoses that can mimic energy storing at the pre-swing phase, can help lifting the foot (toe off), and clearing the foot during swing phase (no stumbling). One of the most promising is the Spring Swing, because this orthosis can be adjusted in force (by means of a spring) needed to get a good foot clearance by using different springs. In stance, this orthosis could give additional stabilization and correction of flaccid equinovarus (often seen in boys with DMD), while plantar flexion and balance movements in the sagittal axis are still possible. By using this dynamic orthosis the minimal contracture in the ankle can be accepted for a good standing position, while during walking

the energy storing mechanism of the orthosis can help toe-off and good foot clearance.

Study objective

This study will consist of two parts. In the primary observational part we will assess kinematic and kinetic walking patterns in Duchenne Muscular Dystrophy. Goal is to asses the correlation between progressive contractures and gait patterns. This will be compared with the findings of Gaudreault (2007) to confirm their hypothesis that contractures of the ankle have a positive effect on gait in DMD.

Secondary, in an intervention study using the same subjects as their own controls (repeated N=1 study), the effects of a dynamic ankle-foot orthosis (AFO) in gait will be evaluated. This to point out whether this AFO leads to a better performance in timed motor performance and fatigue, due to better foot clearance during swing.

If the hypothesis of Gaudreault et al. is correct, we expect to find the Spring Swing having a positive effect on gait economy (meaning better gait characteristics, longer walking distance, and less fatigue). Wearing the AFO's could then lead to a longer ambulation period for boys with DMD.

Study design

The patients will each be tested once without braces, e.g. the observational study, T0. Four weeks later they are studied again with dynamic AFO*s, the intervention study, T1. In between the two sessions the Spring Swing will be custom made by the orthopedic technician, and the boys will be allowed to walk for 2 weeks at home with the orthosis before the second session in the movement laboratory.

In the observational study, clinical and functional tests are run, together with an extended gait analysis in the gait laboratory. In the intervention study, measurements are repeated after using the spring swing for 2 weeks. The spring of the dynamic brace is adjusted to reach zero degrees dorsal flexion in resting position.

Intervention

In the intervention study a dynamic ankle-foot orthosis of OIM (Orthopedische Instrumentmakerij, type *spring swing*) will be used. This brace is made of polypropylene and has a spring attached on the back of the AFO near the

Achilles tendon. It is designed to give an active dorsoflexion moment in swing phase, thus leading to foot clearance. Polypropylene is flexible, allowing small movements in the sagittal axis, as needed for balancing and allowing plantar flexion as seen in toe-walking. The spring can be adjusted to change the external dorsal flexion moment on the ankle created by the orthosis. The orthosis will be custom made and the spring is adjusted to reach zero degrees dorsal flexion in resting position.

Study burden and risks

Burden associated with participation will be limited, since measurements are non-invasive. In addition, it is expected that the interventions are beneficial and may help to gain functional abilities or preserve them for a longer period. If the results are positive, the principles of this training may be applicable to other neuromuscular disorders.*The participants can keep the custom made orthosis if regarded as benificial.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

The study will include at least 6 boys with DNA established diagnosis of Duchenne Muscular Dystrophy walking with minor impairments and unsupported in the community at least for 6 minutes, e.g. Vignos 1-3. Expected is that the age range will be between 6 and 8 years.

Exclusion criteria

Excluded are boys with DMD in combination with other disabling diseases. A questionnaire is sent prior to inclusion to check these items.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2010
Enrollment:	6
Type:	Actual

Medical products/devices used

Generic name:	Ankle-foot orthosis
Registration:	No

Ethics review

Approved WMO Date:	08-09-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL28089.091.09