Pilot Study Comparing night time AFOs with CCDs in the management of ankle contractures

A pilot study to compare night time Ankle Foot Orthosis (AFOs) with Contracture Control Devices (CCDs) in the management of ankle contractures in ambulant boys with Duchenne Muscular Dystrophy (DMD)

Hub Summary

This pilot study aims to identify the sample size required to power a larger scale study to compare AFOs and CCDs in managing ankle range of movement and function in boys with Duchenne muscular dystrophy. It will also explore adherence and patient satisfaction for the two devices.

This study is open to boys who are seen in Newcastle for clinical care and also in adjacent geographical areas to Newcastle who are willing to travel to Newcastle and who meet the inclusion criteria for the study. This includes those whose local physiotherapy providers support their inclusion in the study. Boys will need to be either night splint naive or have only introduced well-fitting night splints within the last 18 months.

Study Number:

Description by Newcastle upon Tyne Hospitals NHS Foundation Trust

Dr Anna Mayhew and Dionne Moat, part of the Neuromuscular Physiotherapy Team in Newcastle are pleased to announce that their pilot study into alternatives to night splints has been opened up to boys in adjacent geographical areas to Newcastle who are willing to travel to Newcastle and who meet the inclusion criteria for the study. This includes those whose local physiotherapy providers support their inclusion in the study. Boys will need to be either night splint naive or have only introduced well-fitting night splints within the last 18 months.

Children with Duchenne muscular dystrophy (DMD) often wear splints called ankle foot orthoses (AFOs). Splints, used in conjunctions with stretching, help them to keep the range of movement in their ankles for as long as possible. When muscles around the joint shorten and become fixed this is known as ankle contractures. Contractures are common in patients with DMD and can often develop in boys as young as 4 or 5 years of age, so it is important we find the best treatments.

This pilot study aims to compare Ankle Foot Orthosis (AFOs) and Contracture Control Devices (CCDs) for managing ankle movement and delaying ankle contractures in ambulant boys with DMD. The study is also designed to compare boys' experience of using these two different devices, as some boys find them uncomfortable. CCDs are dynamic, hinged splints, and have proven to be an effective alternative to static night-time AFOs in other conditions when traditional physiotherapy has been unsuccessful in contracture management. However, local services are often reluctant to fund them, because of a lack of evidence and higher cost.

Primary Outcome Measures

1. This pilot study will be used to estimate sample size required to power a larger scale study. It will aid the design and development of a larger, multi-centre study to ascertain superiority ultimately aiming to build an evidence base for clinicians to guide their clinical decisions regarding orthotic provision.

Can I take part?

Inclusion Criteria

- ✔ Genetic diagnosis of DMD
- ✔ Ankle ROM of between +10 degrees of dorsiflexion and -10 degrees of dorsiflexion.
- ✔ On assessment ROM has either deteriorated or remained the same since prior appointment despite good adherence to current stretching regime
- ✔ Ankle orthotic naïve or supplied with a AFO in the last 18 months that currently fits well
- ✔ Aged between 4 and 10 years of age
- ✔ From JWMDRC clinics or referred to us by a centre which borders us
- ✔ Email or written evidence that the local specialist team are amenable to our oversight of orthotics for the duration of the study

Exclusion Criteria

Trial Status
Trial complete

UK Locations
Newcastle, Fully recruited

Trial Sponsor
Newcastle upon Tyne Hospitals NHS Foundation Trust

Length Of Participation
12 weeks with 4 visits for trial appointments

Recruitment Target
20

Ambulatory
Ambulant

Therapeutic Category
Physiotherapy

Age
4-10

Mutation Specific
All treatment types

Muscle Biopsy
No Muscle Biopsy Required

MRI
No

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- ✖ Significant behavioural issues that would make adherence problematic
- ✖ Previous or current lower limb fracture within the last year
- ✖ Previous tenotomy or other interventions for contracture management
- ✖ Non-English speaking

For contact details and to find out more, please refer to dmdhub.org.

Duchenne UK

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