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Contracture management in Duchenne muscular dystrophy

Submission date
16/10/2023

Recruitment status
No longer recruiting

Registration date
09/02/2024

Overall study status
Completed

Last Edited
18/12/2023

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Duchenne Muscular Dystrophy (DMD) is a condition affecting boys, causing weak muscles and stiff ankles. This makes activities such as walking and climbing stairs difficult. Making sure ankles don't get too stiff may help with these. This is usually done by stretching the ankles every day and wearing splints overnight. A splint is a hard, rigid boot worn to hold the foot in a fixed position, stretching the ankle and making it less stiff. There are different splints which are worn for different lengths of time but we don't know which is the best type. The aim of this study is to determine the feasibility of a full-scale study comparing ankle foot orthoses with contracture control devices in the management of ankle contractures in ambulant boys with DMD.

Who can participate?
Boys aged between 4 and 10 years who have been diagnosed with DMD, who can walk but have stiff ankles and who have either not used splints before or have been given one type of splint in the past year can take part. Initially the study was open only to boys who received care from the neuromuscular team in Newcastle but following some changes, boys from other parts of the country were able to take part.

What does the study involve?
Once agreeing to take part, each boy is randomly put into a group and asked to wear either ankle foot orthoses for at least 8 hours overnight or contracture control devices for 2 hours and both groups are required to complete daily stretches and a daily adherence diary. There are five trial visits with assessments over a 12-week period.

What are the potential benefits and risks of participating?
There is no guarantee that participating will offer any direct benefit but it will help find out important information to help improve how we look after boys with DMD in the future. This is a low-risk trial. Both types of splints have been used in patients with DMD in Newcastle and also in patients with other conditions. Both splints have been reported as being safe and well-tolerated. There is a small chance of discomfort or skin irritation if the splint is not fitted well or applied correctly. If this occurs, it will be assessed and managed during the visits. There is also a

small chance of discomfort from stretching the tight muscles either from the stretch applied by the splint or during the stretches being performed. This often improves and reduces as the boys become used to wearing the splints and performing the stretches.

Where is the study run from?
Trial visit assessments take place at Peacocks which is an orthotics clinic in Newcastle. The team leading the study are based at the John Walton Muscular Dystrophy Research Centre at the Centre for Life in Newcastle (UK)

When is the study starting and how long is it expected to run for?
January 2020 to December 2022

Who is funding the study?
Duchenne UK

Who is the main contact?
Dionne Moat, Dionne.moat1@nhs.net

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
258344

Central Portfolio Management System (CPMS)
47133

Study information

Scientific Title
A pilot study to compare static night time ankle foot orthosis with contracture control device in the management of ankle contractures in ambulant boys with Duchenne muscular dystrophy

Study objectives

A pilot study to determine the feasibility of a full scale study comparing ankle foot orthoses (AFO) with contracture control devices (CCDs) in the management of ankle contractures in ambulant boys with Duchenne Muscular Dystrophy (DMD).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/03/2021, London – Surrey Research Ethics Committee (Nottingham Centre, Nottingham, NG1 6FS, United Kingdom; +44 (0)207 104 8088, +44 (0)207 104 8131; surrey.rec@hra.nhs.uk), ref: 20/LO/1107

Primary study design
Interventional

Study design
Randomized controlled trial pilot study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Duchenne muscular dystrophy

Interventions
A single-centre, single-blinded, randomised control trial pilot study comparing CCDs and AFOs over 12 weeks of intervention. Once agreeing to take part, each boy is randomly put into a group and asked to wear either AFO for at least 8 hours overnight or CCDs for 2 hours and both groups are required to complete daily stretches and a daily adherence diary.

Participants were randomized in a 1:1 ratio. A randomisation application (Sealed Envelope Ltd, 2019) was used.

Group 1 – current standard of care treatment AFO + daily stretches
Splints were worn overnight for at least 8 hours as per recommendations and active or passive ankle stretches as demonstrated by the clinical physiotherapist performed daily as per recommendations

Group 2 – CCDs + daily stretches
Splints were worn for 2 hours daily as per recommendations for this device and active or passive ankle stretches as demonstrated by the clinical physiotherapist performed daily as per recommendations.

There are five trial visits with assessments over a 12-week period. Benefit was evaluated using range of motion (ROM) of ankles and North Star Ambulatory Assessment (NSAA). Inter and intra-rater reliability of these was also calculated using ICC. Patient satisfaction and adherence to both stretches and devices were evaluated using a self-completed diary and a validated satisfaction questionnaire, the Orthotic and Prosthetic User Satisfaction Survey (OPUS).

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ankle Foot Orthosis (AFO), Contracture Control Device (CCD)

Primary outcome(s)
Feasibility of trial design, measured using attrition rate assessed using the number of participants who consented to participate who remained in the study until the end of follow-up at 12 weeks.

Key secondary outcome(s)
1. Ankle ROM measured using goniometry at [baseline T1, baseline T2, week 4 T4, week 8 T5 (no week 8 visits following amendment), week 12 end of study T6]
2. Motor function measured using the North Star ambulatory assessment (NSAA) at baseline T1, baseline T2, week 4 T4, week 8 T5 (no week 8 visits following amendment), week 12 end of study T6
3. Satisfaction with service and device measured using the Orthotics and Prosthetics User's Survey (OPUS) at week 2 T3, week 4 T4, week 8 T5 (no week 8 visits following amendment), week 12 end of study T6
4. Adherence to the intervention measured using a daily diary for 12 weeks

Completion date
02/12/2022

Eligibility

Key inclusion criteria
Inclusion criteria: primary submission:
1. Genetic diagnosis of DMD
2. Ankle ROM of between +10 degrees of dorsiflexion and -10 degrees of dorsiflexion.
3. On assessment ROM has either deteriorated or remained the same since prior appointment despite good adherence to current stretching regime
4. Aged between 4 and 10 years of age
5. Orthotic naïve

AMENDMENT to inclusion criteria: Re-submission:
1. Ankle orthotic naïve or supplied with an AFO in the last 18 months that currently fits well
2. From JWMDRC clinics or referred to us by a centre which borders us
3. Email or written evidence that the local specialist team are amenable to our oversight of orthotics for the duration of the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 Years

Upper age limit
10 Years

Sex
Male

Total final enrolment
5

Key exclusion criteria
1. Significant behavioural issues that would make adherence problematic
2. Previous or current lower limb fracture within the last year
3. Previous tenotomy or other interventions for contracture management
4. Non-English speaking

Date of first enrolment
21/04/2021

Date of final enrolment
20/10/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
John Walton Muscular Dystrophy Research Centre
Newcastle Upon Tyne Hospitals NHS Foundation Trust
Centre For Life
Central Parkway
Newcastle
United Kingdom
NE1 3BZ

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
Duchenne Research Fund

Alternative Name(s)
Duchenne UK, THE DUCHENNE RESEARCH FUND, DRF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dionne Moat (Dionne.moat1@nhs.net).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Adults version 1.4	03/12/2021	06/11/2023	No	Yes
Participant information sheet	Children aged 4 to 6 years version 1.3	03/12/2021	06/11/2023	No	Yes
Participant information sheet	Children aged 6 to 10 years version 1.3	03/12/2021	06/11/2023	No	Yes