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A pilot study of a cross trial with randomised use of ankle foot orthoses and Ligaflex for People with Charcot Marie Tooth disease

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
29/04/2015

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0077170544

Study information

Scientific Title
A pilot study of a cross trial with randomised use of ankle foot orthoses and Ligaflex for People with Charcot Marie Tooth disease

Study objectives
The objective is to pilot a study that compares 3 different types of ankle foot orthosis (AFO) in people with Charcot Marie Tooth disease.

This is a pilot study, so the general aim is test how practical the protocol is and how we might put it into practice in a larger study. As regards consultation this pilot itself will allow consultation for the larger study. The sponsor for the study is the Muscular Dystrophy Campaign, who are one of the main patient bodies concerned in the UK.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Pilot randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Nervous System Diseases: Charcot-Marie Tooth (CMT) Disease

Interventions
Participants will be eight people with CMT with clinical need for an AFO or Ligaflex, using specified criteria. The study is limited to people with CMT, the commonest inherited neuromuscular condition, to reduce variability. Participants may be present or previous users of AFOs, or may never have used them. They will wear three different AFO's during the course of the study: custom made polypropylene, Lygaflex and silicone (Dorset orthopaedic).

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Impairment caused by CMT (record of sensory loss, foot/ankle deformity and motor impairment)
2. Walking velocity over a specified route that involves flat ground and steps
3. Borg scale of perceived exertion of walking around a this route
4. Total heart beat index
5. Walking velocity over 10m

6. Change in joint kinetics/kinematics: ankle, knee, hip and trunk
7. Change in step length
8. Cost of AFO and Ligaflex (including components, orthotist time and patient time and travel)
9. Berg balance scale
10. Number of falls over assessment week
11. Goal Attainment Scale for participant chosen goals of wearing AFO
(same for each AFO)
13. Impact on participation and autonomy scale (IPA)
14. Likert scales regarding comfort, function, cosmesis, ease of.donning and doffing, pain, overall satisfaction, change in abilities, whether the user would use the AFO or Ligaflex if it were prescribed,fulfilment of properties participant chooses for AFO, ranking of preference after final AFO or Ligaflex worn
15. Costs and times of orthoses, their manufacture, health professional contact time, patient time, travel

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/07/2006

Eligibility

Key inclusion criteria
Identified from those attending muscle or neurology clinics in Derby Hospitals. Random sample of 15 approached by letter with patient information sheet. A second letter will be sent if no reply after 2 weeks. If uptake inadequate further letters will be sent after random selection. If an interest is expressed they will be interviewed by the research assistant (RA), either in their own home or in hospital - whichever they prefer. The RA will explain the study in detail, answer queries and take informed consent. Inclusion Criteria:
1. Symptomatic CMT confirmed either on nerve conduction or genetic testing
2. Foot drop in at least one lower limb with grade 4 muscle weakness or lower

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Other disorder affecting ability to walk - as will confound results
2. Lower limb oedema - as will cause difficulties in orthotic fit and make skin breakdown more likely
3. Diabetes mellitus - as may further reduce sensation and also increase risk of skin infection or

pressure sores.
4. Inability to walk 10 metres - as will not be able to participate in gait analysis or 10m walk
5. Age below 16 years old

Date of first enrolment
01/01/2006

Date of final enrolment
01/07/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Derby Hospitals NHS Foundation Trust
Derby
United Kingdom
DE22 3NE

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
Derby Hospitals NHS Foundation Trust (UK), NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2012		Yes	No