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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	Recruitment status	[ ] Prospectively registered
29/09/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/04/2015	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Margaret Phillips

Contact details
Derby Hospitals NHS Foundation Trust
Rehabilitation Research Unit
Derby City General Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE
+44 (0)1332 785681
margaret.phillips@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2006

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
15

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
England

United Kingdom

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

Sponsor details

The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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