

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

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|--------------------------|-----------------------------|--|
| <b>Submission date</b>   | <b>Recruitment status</b>   | <input type="checkbox"/> Prospectively registered    |
| 29/09/2006               | No longer recruiting        | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b> | <b>Overall study status</b> | <input type="checkbox"/> Statistical analysis plan   |
| 29/09/2006               | Completed                   | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b>       | <b>Condition category</b>   | <input type="checkbox"/> 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

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### Contact details

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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

**Study design**

Pilot randomised controlled trial

**Primary study design**

Interventional

**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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/06/2012   |            | Yes            | No              |