

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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| Submission date 29/09/2006 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 29/09/2006 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 29/04/2015 | Condition category Nervous System Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> 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

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
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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 |