ISRCTN94187624 https://doi.org/10.1186/ISRCTN94187624

The effect of two different ankle-foot-orthoses on walking and quality of life in children with Hereditary Motor and Sensory Neuropathy (HMSN) - also known as Charcot-Marie Tooth (CMT) Disease.

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 11/04/2014	**Condition category** Nervous System Diseases	

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

N0170141303

Study information

Scientific Title

Study objectives
Do silicone ankle foot orthosis (AFOs) offer similar benefits to children with Hereditary Motor Sensory Neuropathy (HMSN) in terms of walking and Quality of Life measures as do traditional AFOs?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised cross-over study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Interventions
Randomised cross-over study. Gait analysis performed in Human Performance Laboratory

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The benefits of silicone over traditional AFOs

Secondary outcome measures
Not provided at time of registration

Overall study start date
15/05/2004

Completion date
15/11/2005

Eligibility

Key inclusion criteria
1. Six children with Charcot-Marie Tooth disease
2. Children aged 4-16 with proven HMSN and therefore foot drop

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
16 Years

Sex
Not Specified

Target number of participants
6

Key exclusion criteria
Children with no foot drop.

Date of first enrolment
15/05/2004

Date of final enrolment
15/11/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen's Medical Centre
Nottingham
United Kingdom
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Nottingham City Hospital NHS 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