

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.

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|----------------------------------------|------------------------------------------------------|------------------------------------------------------|
| Submission date 30/09/2005 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 30/09/2005 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 11/04/2014 | Condition category Nervous System Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

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
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

Study type(s)

Not Specified

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(s)

The benefits of silicone over traditional AFOs

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

4 years

Upper age limit

16 years

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Queen's Medical Centre

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Nottingham City Hospital NHS 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