

Strengthening hip muscles to improve walking distance in people with Charcot-Marie-Tooth disease

Submission date
08/04/2009

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
12/05/2009

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
23/05/2016

Condition category
Nervous System Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

12

Study information

Scientific Title

Strengthening hip muscles to improve walking distance in people with Charcot-Marie-Tooth disease: a randomised single-blinded crossover trial

Study objectives

To ascertain whether training the hip flexor muscles allows them to increase in strength. The study then aims to explore whether these strength changes allow the hip flexor muscles to be utilised for longer when walking and thus improve walking endurance.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Barnet, Enfield and Haringey Local Research Ethics Committee, 27/02/2009, ref: 09/H0723/6

Primary study design

Interventional

Study design

Randomised single-blinded crossover trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Charcot-Marie-Tooth disease

Interventions

There will be two 16-week periods with an 8-week washout phase post-exercise intervention. Subjects will be assigned to two groups and will either continue their normal activities or will target the hip flexors muscles. Measures of strength and functional ability will be recorded at the start and finish of each 16-week period. Thirty two subjects will be randomly allocated to the two groups. A blinded assessor will record the outcome measures.

Intervention Type

Behavioural

Primary outcome(s)

Isometric muscle strength of the hip flexors - measured using fixed myometry.

Timepoints:

Group A: Baseline (0 weeks), post-intervention (16 weeks), post-washout (24 weeks), final measurement (40 weeks)

Group B: Baseline (0 weeks), post-control (16 weeks), post-intervention (32 weeks), post-washout (40 weeks)

Key secondary outcome(s)

1. Six Minute Timed Walk Test: change in maximal walking distance in 6 minutes and peak heart rate
2. Walking speed: using a Timed 10 Metre Walk Test
3. Perceived exertion during the Six Minute Timed Walk Test: using the Borg 15-point scale
4. Heart rate and Physiological Cost Index (PCI) during the Six Minute Timed Walk Test: using a

heart rate monitor

5. Fatigue: assessed using the Fatigue Severity Scale (FSS)

6. Perception of walking ability: Walk-12 scale

7. Disease severity: Charcot-Marie-Tooth Symptom/Sign Score (CMTSS)

8. Physical limitations: Overall Neuropathy Limitations Scale (ONLS)

9. Pain: assessed using the Visual Analogue Scale (VAS)

Timepoints:

Group A: Baseline (0 weeks), post-intervention (16 weeks), post-washout (24 weeks), final measurement (40 weeks)

Group B: Baseline (0 weeks), post-control (16 weeks), post-intervention (32 weeks), post-washout (40 weeks)

Completion date

31/12/2009

Eligibility

Key inclusion criteria

People will be recruited provided all of the following criteria are satisfied:

1. Clinical diagnosis of Charcot-Marie-Tooth disease (CMT)
2. Aged 18 to 70 years, either sex
3. Able to walk for 50 m with or without a walking aid or orthotic devices
4. Signed informed participant consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

People will be excluded from the study if one or more of the following criteria apply:

1. Presence of other significant neurological disorders (such as multiple sclerosis, cerebrovascular diseases, movement disorders), or major comorbidities (e.g., definite cognitive impairment, psychiatric disease, heart or lung failure, orthopaedic or rheumatological disorders)
2. Limb surgery during the six months prior to screening (or planned before final assessment)
3. Severe congenital hip dysplasia associated with CMT
4. Aged over 70 or under 18 years
5. Women of child-bearing age only if they are pregnant at the inclusion into the study or plan to become pregnant during the study (people agreeing not to become pregnant during the study)

must take appropriate contraceptive methods - contraceptive pill, intrauterine device, barrier methods)

Date of first enrolment

01/04/2009

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

National Hospital for Neurology and Neurosurgery

London

United Kingdom

WC1N 3BG

Sponsor information

Organisation

University College London Hospitals NHS Foundation Trust (UK)

ROR

<https://ror.org/042fqyp44>

Funder(s)

Funder type

Charity

Funder Name

Muscular Dystrophy Campaign (MDC) (UK)

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?
Results article	results	01/12/2014		Yes	No