ISRCTN87551289 https://doi.org/10.1186/ISRCTN87551289

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

Submission date
08/04/2009

Recruitment status
No longer recruiting

Registration date
12/05/2009

Overall study status
Completed

Last Edited
23/05/2016

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Mary Reilly

Contact details
MRC Centre for Neuromuscular Diseases
National Hospital for Neurology and Neurosurgery
Queen Square
London
United Kingdom
WC1N 3BG
+44 (0)20 7837 3611 ext. 3457
m.reilly@ion.ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design
Randomised single-blinded crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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)

Secondary outcome measures
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)

Overall study start date
01/04/2009

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

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
32

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
England

United Kingdom

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)

Sponsor details
Joint UCLH & UCL Biomedical Research Unit (R&D)
Rosenheim Wing
Ground Floor
25 Grafton Way
London
England
United Kingdom
WC1E 5DB
-
philip.diamond@uclh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.uclh.nhs.uk/

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Charity

Funder Name
Muscular Dystrophy Campaign (MDC) (UK)

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	01/12/2014		Yes	No