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Effects of neuromuscular stimulation on quadriceps in chronic obstructive pulmonary disease (COPD)

Submission date 22/11/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 03/05/2011	**Overall study status** Completed	
Last Edited 02/02/2017	**Condition category** Respiratory	

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

Protocol Version 1

Study information

Scientific Title
The effects of unilateral neuromuscular stimulation on quadriceps muscle morphology, architecture and function in chronic obstructive pulmonary disease

Study objectives
The overarching hypothesis of this proposal is that neuromuscular electrical stimulation (NMES) results in changes to quadriceps microstructure, architecture and function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands Research Ethics Committee, 11/11/2010, ref: 10/H1208/73

Study design
Single centre parallel design randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled 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
Respiratory disease (chronic obstructive pulmonary disease)

Interventions
1. Single leg resistance training (control):
Three supervised quadriceps resistance training sessions per week for 6 weeks.

2. Single leg neuromuscular elctrical stimulation (experimental):
Three supervised and two unsupervised sessions of neuromuscular electrical stimulation per week for 6 weeks.

Intervention duration: 6 weeks
Total follow up: 6 weeks (time of intervention)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Muscle Mass: quadriceps mass change at 6 weeks

Secondary outcome measures
1. Neural Adaptations to Training at 6 weeks
2. Muscle Architecture including pennation angle at 6 weeks
3. Muscle Morphology including fibre type at 6 weeks
4. Muscle hypertrophy including satellite cell activity and cross sectional area at 24 hours and 6 weeks
5. Acute local inflammation response at 24 hours and 6 weeks
6. Functional change in quadriceps strength at 6 weeks

Overall study start date
01/01/2011

Completion date
31/07/2011

Eligibility

Key inclusion criteria
1. Diagnosis of COPD
2. Forced expiratory volume in one second (FEV1) less than 50% predicted
3. FEV1/forced vital capacity (FVC) ratio less than 70%
4. Medical Research Council (MRC) dyspnoea score greater than 3
5. Clinically stable at time of recruitment (greater than 4 weeks exacerbation free)
6. Aged greater than 40 years, both sexes

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Uses long-term oral corticosteroids
2. Uses anticoagulation (e.g. warfarin)
3. Impaired clotting

4. Long-term oxygen therapy
5. Comorbid condition preventing exercise training, causing exercise limitation
6. Pulmonary rehabilitation in last 12 months
7. Condition causing intramuscular inflammation (e.g. type two diabetes [T2D], rheumatoid arthritis, inflammatory bowel disease)

Date of first enrolment
01/01/2011

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
CLAHRC Rehabilitation Theme Office (Ward 25)
Leicester
United Kingdom
LE3 9QP

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

Sponsor details
c/o Carolyn Maloney
Research & Development Office
Leicester General Hospital
Gwendolen Road
Leicester
England
United Kingdom
LE5 4PW

Sponsor type
Hospital/treatment centre

Website
http://www.uhl-tr.nhs.uk/ourservices/rd

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Collaboration for Leadership in Applied Health Research and Care (CLAHRC)

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