ISRCTN15985261 https://doi.org/10.1186/ISRCTN15985261

Investigating the effect of bilateral quadriceps NeuroMuscular Electrical Stimulation (NMES) on exercise capacity in patients with severe chronic obstructive pulmonary disease

Submission date
31/05/2012

Recruitment status
No longer recruiting

Registration date
31/05/2012

Overall study status
Completed

Last Edited
01/12/2016

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
People with chronic obstructive pulmonary disease (COPD) often experience a reduced ability to exercise, which affects their independence and quality of life. Several factors contribute to this including leg muscle weakness. Exercise can help but even simple forms, e.g. walking, can be difficult when out of breath. An alternative is neuromuscular electrical stimulation (NMES) which uses a small battery-operated stimulator and pads placed over each thigh to produce a comfortable contraction and relaxation of the underlying muscles. Several small studies have found 4–6 week programmes to benefit patients but larger studies are required to confirm these findings.

Who can participate?
People diagnosed with COPD, attending clinics at the Kings College Hospital NHS Foundation Trust may be invited to take part by their usual clinical team.

What does the study involve?
In this study 52 people with severe COPD will be allocated to receive either active or sham (dummy) NMES to the thigh muscles. Both programmes will consist of 30 minutes of daily stimulation for 6 weeks, but the level will be set to either allow muscle contraction (active) or provide sensation only (dummy). Before and after the programme participants ability to exercise, thigh muscle strength and size, physical activity level and quality of life will be assessed.

What are the possible benefits and risks of participating?
We hope that using NMES will help keep participants leg muscles strong and the information we get from this study should help us provide better care for people with COPD and will help confirm if NMES can benefit people with COPD unable to complete traditional forms of exercise. If successful, this may help this group maintain their independence for longer. It is however possible some participants will not gain any benefits from using NMES. NMES has been used in a wide range of medical conditions and there should be no serious side effects. People sometimes

feel slight muscle soreness after first using NMES because it is a form of exercise, but this generally settles after a day or two.

Where is the study run from?
The study will run from Kings College Hospital NHS Foundation Trust.

When is study starting and how long is it expected to run for?
The study start in June 2012 and run approximately two years.

Who is funding the study?
National Institute for Health Research (NIHR)

Who is the main contact?
Dr Matthew Maddocks
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12017

Study information

Scientific Title

A randomised placebo-controlled trial investigating the effect of bilateral quadriceps NeuroMuscular Electrical Stimulation (NMES) on exercise capacity in patients with severe chronic obstructive pulmonary disease

Acronym
NMES

Study objectives
People with chronic obstructive pulmonary disease (COPD) often experience a reduced ability to exercise, which affects their independence and quality of life. Several factors contribute to this including leg muscle weakness.

Exercise can help but even simple forms, e.g. walking, can be difficult when out of breath. An alternative is neuromuscular electrical stimulation (NMES) which uses a small battery-operated stimulator and pads placed over each thigh to produce a comfortable contraction and relaxation of the underlying muscles. Several small studies have found 4-6 week programmes to benefit patients but larger studies are required to confirm these findings.

Fifty-two people with severe COPD will be allocated to receive either active or sham NMES to the thigh muscles. Both programmes will consist of 30 minutes of daily stimulation for 6 weeks, but the level will be set to either allow muscle contraction (active) or provide sensation only (placebo). Before and after the programme participants ability to exercise, thigh muscle strength and size, physical activity level and quality of life will be assessed. Findings will confirm if NMES can benefit people with COPD unable to complete traditional forms of exercise. If successful, this may help this group maintain their independence for longer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Camberwell St Giles NRES Committee, ref:12/LO/0263

Study design
Randomised; Interventional; Design type: Treatment

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
Chronic obstructive pulmonary disease

Interventions
Active, NMES to the quadriceps for 30min daily for 6 weeks (frequency 50Hz, pulse width 350μs, duty cycle 11-50%, amplitude 0-120mA over 1000O). The proportion of the treatment duration which is active, i.e. the stimulation phase of the duty cycle, will increase on a weekly basis from 11% to 25% to 50%, remaining constant thereafter.

Control, Placebo NMES to the quadriceps for 30min daily for 6 weeks using levels of stimulation detectable by the patient but not able to elicit a tetanic muscle contraction (frequency 50Hz, pulse width 350μs, duty cycle 11-50%, amplitude 0-20mA).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Six-minute walk test (6MWT) at baseline, 6 and 12 weeks

Secondary outcome measures
1. Quadriceps function and size; assessed by quadriceps maximum voluntary contraction and twitch with femoral nerve stimulation, time for twitch to decline to 70% of maximum with repetitive transcutaneous stimulation, rectus femoris cross sectional area with ultrasonography and fat free mass by bioimpedence (kg).
2. Exercise capacity: assessed by 6MWT distance (m) at 12 weeks
3. Physical activity level: mean daily step count, up/down transitions and time spent upright
4. Health-related quality of life; overall health on EQ5D visual analogue scale (0–100), St Georges
5. Respiratory Questionnaire and Chronic Respiratoary Disease Questionnaire
6. Service utilisation; formal and informal care 12 weeks assessed by Client Service Reciept Inventory
7. Patients' experiences: semi-structured interviews in a sub-group of patients at 6 weeks

Overall study start date
17/05/2012

Completion date
17/05/2014

Eligibility

Key inclusion criteria
1. >=18 years of age
2. Diagnosis of COPD [forced expiratory volume in the first one second to the forced vital capacity of the lungs (FEV1: FVC ratio <=70%)]
3. Severe respiratory impairment (GOLD stage III/IV; FEV1 <=50% predicted)
4. Incapacitating breathlessness (MRC dyspnoea score 4/5)
5. Able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 52; UK Sample Size: 52

Key exclusion criteria
1. Cardiac pacemaker
2. Co-existing neurological condition
3. Change in medication or exacerbation requiring admission in preceding 4 weeks
4. Recent systemic corticosteroids (>=5 consecutive days in last 4 weeks)
5. Current regular exerciser (structured training >=3 times/week within last month)
6. Adults unable to consent for themselves

Date of first enrolment
17/05/2012

Date of final enrolment
17/05/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cicely Saunders Institute
London
United Kingdom
SE5 9PJ

Sponsor information

Organisation

King College Hospital (UK)

Sponsor details
Child Health
Denmark Hill
London
England
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/044nptt90

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Doctoral Research Fellowship

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	01/01/2016		Yes	No