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An investigation into the effect of neuromuscular electrical stimulation (NMES) and pulmonary rehabilitation in patients with chronic obstructive pulmonary disease (COPD)

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28/09/2007

Recruitment status
Stopped

Registration date
28/09/2007

Overall study status
Stopped

Last Edited
25/07/2012

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
N0265183531

Study information

Scientific Title

Study objectives
The aim of this study is to establish whether the addition of neuromuscular electrical stimulation (NMES) to a standard programme of pulmonary rehabilitation offers additional clinical benefit in patients with chronic obstructive pulmonary disease (COPD). Pulmonary rehabilitation has been consistently effective in improving exercise capacity and health status in patients with COPD and is now recommended as part of the management of such individuals. Recently there has been interest in the systemic effects of COPD including peripheral muscle weakness that is a limiting factor to exercise in patients with COPD. Specific stimulation of these muscles may improve their metabolic and physiological function and thus alleviate premature exercise termination as a result of peripheral muscle fatigue. This may then allow greater benefits to be obtained during pulmonary rehabilitation in terms of both exercise tolerance and health status.

Secondary research questions are as follows:
1. Is it feasible to carry out NMES at the same time as pulmonary rehabilitation in patients with COPD?
2. Does the benefit depend on the severity of disease?
3. Does the benefit depend on the baseline physiological status or strength of the peripheral skeletal muscles?
4. Does NMES influence the rate of detraining after the programme has finished?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
The study design will be a single blind randomised controlled study in which the patients will be randomised to one of two groups:
1. Pulmonary rehabilitation plus NMES
2. Pulmonary rehabilitation plus sham NMES
Patients will each be given an identical NMES device and therefore will not be aware which study group they are in.

COPD patients will be recruited from those attending for the 8-week pulmonary rehabilitation (PR) programme at the Lung Investigation Unit, Queen Elizabeth Hospital, University Hospital Trust, Birmingham. Following recruitment and consent patients will undergo a baseline evaluation prior to the exercise training programme that will be repeated at the end of the 8-week training regime. The assessment pre- and post-pulmonary rehabilitation will require

patients to attend the hospital for three visits at each time point in order to complete the baseline and outcome measurements (N.B. patients already undergo two assessment visits at the start and end of the current pulmonary rehabilitation programme, thus participation in the research study will only require them to attend the laboratory for one extra visit at the start and end of the programme). Patients will also be assessed on these occasions as to whether they require additional educational support with regard to medication, inhaler technique, dietary advice and social support. Those measurements highlighted with an asterisk indicate those that are not part of the current protocol for patients undergoing assessment for pulmonary rehabilitation.

Assessment Day 1:
1. Anthropometric measurements (weight, height)
2. Peak oxygen uptake
3. Endurance exercise capacity
4. Health status (36-item short form health survey [SF36], Chronic Respiratory Disease Questionnaire [CRQ], MRC scale* and Hospital Anxiety and Depression [HAD]* questionnaires)
5. Habitual activity (patients will be issued with an activity monitor for use at home)

Assessment Day 2:
1. Lung function
2. Body composition (skin fold thicknesses, body impedance)
3. Walking distance (incremental shuttle walking test [ISWT] distance)
4. Respiratory muscle strength (Pi max and Pe max)*
5. Hand grip strength (HGS)*

Assessment Day 3:
1. Quadriceps force*
2. Calf muscle blood flow capacity*

Pulmonary Rehabilitation Programme:
Patients will attend the programme three times weekly for a period of 8 weeks. During each visit they are required to exercise for 45 minutes at an intensity of 80% of their peak oxygen uptake. Thus all patients receive a protocol that is individualised to their exercise capacity. The duration and intensity of exercise is gradually increased from 30 to 45 minutes over the first 2 - 3 weeks of the programme in order to provide a gradation of work over the initial training sessions. An interval training approach is adopted where appropriate in order to allow patients with excessive dyspnoea to recover between excessive bouts, e.g. patients exercise for 4 minutes and then have 1 minute rest. N.B. In some patients it may be difficult to achieve 30 minutes in the first exercise session therefore patients may start at 20 minutes and then build up. Similarly, not all patients will achieve 45 minutes at the end of the programme. The exercise performed will be aerobic training using a combination of cycling, walking (treadmill) and stepping. Patients will attend the hospital in small groups of two or three and rotate around the equipment during the 45 minute session, e.g. 15 minutes on each exercise modality. Patients that show significant oxygen desaturation (greater than 4% to less than 90%) will be given supplemental oxygen during the training in order to maintain the saturation above 90% and to prevent excessive dyspnoea that may limit training.

Neuromuscular electrical stimulation and sham stimulation:
Active electrical stimulation will be applied to the quadriceps and calf (muscles of both legs) using Neurotech NT2000 programmable portable constant voltage muscle stimulators (Biomedical Research Ltd., Ireland) for a total of 8 weeks. Each quadriceps muscle will be stimulated for 15 minutes per day at a frequency of 50 Hz on three days of the week. On three

alternate days of the week, the calves will be stimulated twice daily at a frequency of 8 Hz for 15 minutes. During stimulation, patients will be advised to be seated with the foot resting flat on the floor in order to provide some
resistance load to the contracting muscle. The stimulators record usage as a measure of compliance and patients will be given a diary to record date, time and level stimulation output. For sham stimulation, stimulators will be programmed to deliver pulses at high frequency (90 Hz) but short duration which provides a tingling sensation but no active muscle contraction and controls for placebo effect.

Please note that this trial was stopped because of poor recruitment and staff shortages.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Improvement in exercise tolerance assessed by the Incremental Shuttle Walking Test. This will be assessed by comparing the magnitude of the improvement in walking distance between patients randomised to receive pulmonary rehabilitation alone and those receiving pulmonary rehabilitation plus NMES.

Key secondary outcome(s))
1. Changes in peak oxygen uptake
2. Changes in endurance exercise performance
3. Changes in health status
4. Changes in muscle function
5. Changes in calf muscle blood flow capacity

All these will be assessed in terms of firstly, whether there has been an overall improvement in the function in each group and secondly, whether there is a statistically significant difference in the magnitude of the improvement between patients receiving pulmonary rehabilitation alone and those receiving pulmonary rehabilitation plus NMES.

Completion date
26/08/2007

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Diagnosis of COPD
2. Declining functional capacity (Medical Research Council [MRC] grade 3 and above)
3. On optimal pharmacological treatment
4. Clinical stable (no exacerbation within 4 weeks of initial assessment and not taking antibiotics /oral steroids for an acute infection)
5. Smokers will be included
6. Patients receiving long-term oxygen therapy (LTOT) will be included

7. Evidence of nutritional depletion - body weight less than 90% of ideal body weight (IBW) and /or fat-free mass (FFM) less than 69% IBW (males) and 67% IBW (females)
8. Evidence of peripheral muscle weakness (quadriceps force less than 80% predicted and/or hand grip strength less than 80% predicted)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
1. Unstable heart disease (and patients with pacemakers)
2. Untreated hypertension
3. Untreated hypothyroidism
4. Angina
5. Pregnancy
6. Arthritis (such that patient is unable to perform an exercise test and take part in an exercise training programme) or other mobility problems that will limit exercise capacity
7. Patients unable (or unwilling) to attend the hospital three times weekly for exercise training sessions
8. Patients unwilling to commit to lifestyle changes
9. Patients having an acute exacerbation of their disease within the previous 4 weeks

Date of first enrolment
26/08/2006

Date of final enrolment
26/08/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Respiratory Medicine
Birmingham
United Kingdom
B29 6JD

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham 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