ISRCTN40579508 https://doi.org/10.1186/ISRCTN40579508

Neuromuscular electrical stimulation (NMES) as an adjunct to pulmonary rehabilitation in patients with COPD

Submission date 04/12/2017	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol
Registration date 14/12/2017	**Overall study status** Stopped	[_] Statistical analysis plan [_] Results
Last Edited 11/10/2019	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

Chronic obstructive pulmonary disease (COPD) is a disease of the lungs that results in narrowing of the airways. Although mainly a disease of the lungs, research has shown that the leg muscles in patients with COPD are weaker than those in healthy people of a similar age. Leg muscle weakness in COPD has been shown to reduce exercise ability, which can affect independence and quality of life. Currently the only effective treatment at reversing muscle weakness in patients with COPD is through Pulmonary Rehabilitation (PR). PR is a supervised programme that consists of exercise training and education and has been shown to improve exercise capacity and quality of life; however the effects of PR on muscle strength are modest. In patients who have muscle weakness, neuromuscular electrical stimulation (NMES) may offer a means of enhancing muscle strength. NMES uses a small battery-operated machine and pads, which are placed over each thigh to produce a comfortable stimulation of the underlying muscles. Several small research studies have shown that using NMES in patients with COPD has improved leg muscle strength. However, there is very little data examining the role of NMES in enhancing the benefits of PR. Therefore we want to examine whether NMES of the thigh muscle in addition to PR can increase leg muscle strength and function more than PR alone in people with COPD. Therefore the aim of this study is to examine whether NMES of the thigh muscle in addition to a pulmonary rehabilitation programme can increase leg muscle strength and function more than pulmonary rehabilitation alone in people with COPD.

Who can participate?

Adults aged 40 years old who COPD and have been referred to PR.

What does the study involve?

Participants are randomly allocated to one of two groups .Those in the first group receive the bilateral NMES of the quadriceps for 30 minutes daily for eight weeks in addition to an eight-week PR course. Those in the second group receive a “sham” therapy for 30 minutes daily for eight weeks in addition to an eight-week PR course.

What are the possible benefits and risks of participating?
It is hoped that the NMES device will help enhance the benefits of pulmonary rehabilitation on participants leg muscles however; it is possible that participants may not gain any additional benefits from using the NMES device. The information that is gained from this study should help us provide better care for people with COPD.There are no significant risks associated with participating in the proposed research. There is a very small risk of a sports related injury. This will be minimised by encouraging gentle warming-up exercises prior to performing the tests. The NMES devices have been used in a wide range of medical conditions and there should be no side effects. Participants may feel a 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?
Harefield Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2017 to March 2022

Who is funding the study?
Royal Brompton & Harefield NHS Foundation Trust (UK)

Who is the main contact?
Ms Sarah Jones (Scientific)

Contact information

Type(s)
Scientific

Contact name
Ms Sarah Jones

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Harefield Hospital
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
36500

Study information

Scientific Title
Quadriceps neuromuscular electrical stimultaion (NMES) as an adjunct to pulmonary rehabilitation in patients with COPD and quadriceps weakness - a randomised double-blind placebo-controlled trial

Acronym
QUEST-PR

Study objectives
It is hypothesised that those patients with COPD receiving active NMES in addition to an eight-week outpatient pulmonary rehabilitation programme will have improved lower limb muscle function, exercise capacity and health related quality of life compared to those in the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Riverside Research Ethics Committee, 16/11/2017, ref: 17/LO/1830

Study design
Randomised; Interventional; Design type: Treatment, Device, Rehabilitation

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 lower respiratory diseases

Interventions
Participants are randomly allocated to one of two groups: the control or the intervention group.

Control Group: “Sham” bilateral NMES of the quadriceps for 30 minutes daily for eight weeks in addition to an eight-week pulmonary rehabilitation course.

Intervention Group: “Active” bilateral NMES of the quadriceps for 30 minutes daily for eight weeks in addition to an eight-week pulmonary rehabilitation course.

Participants are assessed for their cycle endurance, their walking exercise, functional performance, lower limb muscle strength and mass, and health related quality of life.

Intervention Type
Other

Primary outcome measure
Cycle endurance measured using constant work rate test at 80% workload at baseline and eight-weeks.

Secondary outcome measures
1. Walking exercise capacity measured using incremental shuttle walk test (ISW) and endurance shuttle walk test (ESW) at baseline and eight-weeks
2. Functional performance measured using short physical performance battery (SPPB), stair climb power test (SCPT) and the self-paced step test at baseline and eight weeks
3. Lower limb muscle strength and mass as measured by quadriceps maximal voluntary contraction, bioelectrical impedance analysis and ultrasound at baseline and eight weeks
4. Health related quality of life as measured by COPD assessment test and EQ5D5L at baseline and eight-weeks

Overall study start date
04/04/2017

Completion date
31/03/2022

Reason abandoned (if study stopped)
Staff departure

Eligibility

Key inclusion criteria
1. Aged ≥40 years
2. Confirmed diagnosis of COPD according to GOLD guidelines
3. Referred for outpatient PR
4. Quadriceps muscle weakness defined as quadriceps maximum voluntary contraction (QMVC, kg) / Body Mass Index (BMI, kg/m2) ratio ≤1.2
5. Able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 108; UK Sample Size: 108

Key exclusion criteria
1. Any condition that precludes providing informed consent e.g. cognitive impairment or inadequate English
2. Participation in an exclusively home-based pulmonary rehabilitation programme
3. Predominant neuromuscular or joint limitation to walking or cycling
4. Co-existing progressive neurological or neuromuscular condition
5. Contraindication for unsupervised use of NMES including pregnancy, implanted cardiac pacemaker, skin abrasion, metallic lower limb prosthesis
6. Formal supervised pulmonary rehabilitation in the preceding six months
7. Unstable cardiac conditions including unstable angina, unstable congestive heart failure, severe aortic stenosis, suspected aortic aneurysm
8. Active or suspected thromboembolic disease including recent pulmonary embolism
9. An acute exacerbation requiring antibiotics within the preceding four weeks

Date of first enrolment
02/01/2018

Date of final enrolment
01/01/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Harefield Hospital
Hill End Road
Harefield
Middlesex
United Kingdom
UB9 6JH

Sponsor information

Organisation
Royal Brompton & Harefield NHS Foundation Trust

Sponsor details
Royal Brompton Hospital
Sydney Street
London
England
United Kingdom
SW3 6NP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02218z997

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The result of this study plan to be published in a high-impact peer reviewed journal in 2022.

Intention to publish date
01/12/2022

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No