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ACE inhibitors to augment the effects of pulmonary rehabilitation in COPD

Submission date	**Recruitment status**	[X] Prospectively registered
09/11/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/11/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/11/2016	Respiratory	

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is a combination of chronic bronchitis (infection of the main airways of the lungs) and emphysema (destruction of lung tissue) usually caused by smoking. It is very common, affecting up to 2.4 million people in the UK. Because breathing capacity is reduced, patients get breathless with exercise and become less active. This in turn causes a loss of fitness which leads to worse breathlessness. This vicious spiral of inactivity can be helped by a supervised exercise program known as pulmonary rehabilitation. Muscle weakness occurs in about one third of people with COPD and is associated with a reduced ability to do daily activities and with a greater risk of death. Because COPD is so common it is only possible to provide short exercise programs and these are only available to a small proportion of patients. An additional problem is that the muscles of people with lung disease do not necessarily respond to exercise in the same way as healthy people. There is an excessive stress response in the muscle and this blocks some of the beneficial effects of exercise. Researchers have been trying to find ways to increase the response to exercise training especially because of the limited resources available. Laboratory experiments and some work in humans suggest that a class of medication called ACE inhibitors would provide a more 'oxidative' type of muscle which would have greater endurance properties, to enable people to do daily activities more easily. ACE inhibitors are commonly used as a treatment for high blood pressure.

Who can participate?
Patients with COPD who are limited in their daily activities.

What does the study involve?
Patients will take part in an 8-week pulmonary rehabilitation study. Half of them will take an ACE inhibitor daily and half will take a placebo (dummy) tablet daily. We will measure their exercise capacity on an exercise bike before and after the program to see if the ACE inhibitor group show more improvement. We will also take small samples of muscle and blood before and after so that we can study the molecular mechanisms involved and how these relate to changes in exercise capacity.

What are the possible benefits and risks of participating?
Because ACE inhibitors are an established (and relatively cheap) class of drug, if the study is

positive it would be possible to start using them for this purpose in the clinic quickly, potentially benefiting a large number of people.

Where is the study run from?
Royal Brompton Hospital, London (UK)

When is the study starting and how long is it expected to run for?
December 2012 to March 2015

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Dr Nicholas Hopkinson
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V1 16th January 2012

Study information

Scientific Title
ACE inhibitors to augment the effects of pulmonary rehabilitation in COPD

Acronym

ACE-EPIC

Study objectives
The objective of the study is to establish whether enalapril can augment the effects of pulmonary rehabilitation on patients with COPD. This will focus on exercise capacity measured using cycle ergometry but data will also be collected on strength, body composition, physical activity level and health related quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Bloomsbury Research Ethics Committee, 21/03/2012, ref: 12/LO/0331

Study design
Single centre double blind placebo controlled parallel group study

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
COPD

Interventions
Treatment will with 10mg enalapril or matched placebo once daily. Drug and placebo will be encapsulated by Royal Free Pharmacy. Drug will be dispensed from the pharmacy at Royal Brompton and Harefield NHS Foundation Trust.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Increase in peak workload achieved on a cycle ergometer following a rehabilitation program compared between enalapril and placebo treated patients.

Secondary outcome measures
1. Quadriceps strength
2. Six minute walk distance
3. HRQOL (CAT score)
4. Physical activity level (SenseWear armband)

Overall study start date
01/12/2012

Completion date
31/03/2015

Eligibility

Key inclusion criteria
Adults with GOLD stage II-IV COPD and a clinical indication for pulmonary rehabilitation (MRC score of 3 or more or functionally limited)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Clinically unstable patients (within one month of exacerbation)
2. Those with a permanent pacemaker (which is a contraindication to magnetic stimulation), or significant co-morbidity
3. Patients with an accepted indication for ACE inhibition (left ventricular dysfunction, diabetes) or a contraindication such as renovascular disease
4. Creatinine clearance (estimated) <50)
5. Hypotension
6. Use of anticoagulants (contra-indication to biopsy) or ACE-I or ATII receptor antagonists
7. Allergy to ACE-inhibitors
8. Pregnancy

Date of first enrolment
01/12/2012

Date of final enrolment
31/03/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Brompton Hospital
Sydney Street
Chelsea
London
United Kingdom
SW3 6NP

Sponsor information

Organisation
Imperial College London (UK)

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Sponsor type
University/education

Website
http://www3.imperial.ac.uk/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council [MRC] (UK) ref: MR/J000620/1

Results and Publications

Publication and dissemination plan
Planned publication of results in a peer reviewed journal.

Intention to publish date
01/06/2016

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	01/12/2016		Yes	No
HRA research summary			28/06/2023	No	No