

ACE inhibitors to augment the effects of pulmonary rehabilitation in COPD

Submission date 09/11/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/11/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/11/2016	Condition category Respiratory	<input type="checkbox"/> Individual participant data

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

Dr Nicholas Hopkinson

Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

Royal Brompton Hospital

Sydney Street

Chelsea

London

United Kingdom

SW3 6NP

Sponsor information

Organisation

Imperial College London (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

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