# Effect of dietary nitrate supplementation on exercise performance in chronic obstructive pulmonary disease (COPD)

| Submission date 11/04/2013          | <b>Recruitment status</b><br>No longer recruiting | [X] Prospectively registered [] Protocol     |
|-------------------------------------|---|--|
| <b>Registration date</b> 22/04/2013 | <b>Overall study status</b><br>Completed          | [_] Statistical analysis plan<br>[X] Results |
| Last Edited<br>04/11/2016           | <b>Condition category</b><br>Respiratory          | Individual participant data                  |

## Plain English summary of protocol

Background and study aims

Patients with chronic obstructive pulmonary disease (COPD), which is a combination of chronic bronchitis and emphysema, are limited in their daily activates because of breathlessness. However, there is increasing evidence that their muscle function is also reduced which can further limit them, so we are investigating a dietary supplement that may be helpful. Muscle metabolism and blood flow are influenced by a substance called nitric oxide (NO). Levels of this can be influenced by dietary nitrate consumption (found in leafy green vegetables and especially in beetroot). There is evidence that beetroot juice can improve exercise performance in athletes and we want to test whether it will improve exercise performance in people with COPD.

Who can participate? We will study 25 people with COPD.

#### What does the study involve?

After baseline assessments of lung function and exercise capacity, patients will perform two maximum exercise tests. One after consuming 70mls of beetroot juice and one after consuming 70mls of beetroot juice treated to remove the nitrate (placebo). They taste identical and patients and researchers will not know which they have consumed. The primary endpoint (or (measure of success) of the study is the time that patients can cycle on a bike in our laboratory at a workload that is 70% of the maximum they can reach. Oxygen consumption and muscle metabolism (using a technique called near infrared spectroscopy) will be assessed. We will take blood samples to monitor the effect of the juice/placebo on nitrate levels.

What are the possible benefits and risks of participating?

The procedures are all routine so no risks are anticipated: If positive, this initial study would lead to a larger research study to evaluate the use of this supplement more widely in patients with COPD.

Where is the study run from? The study is being performed at The Royal Brompton Hospital and is supported by Imperial College (UK).

When is the study starting and how long is it expected to run for? It is expected to run from the beginning of May 2013 until the end of 2014.

Who is funding the study? It is funded from Royal Brompton Hospital Departmental funds (UK).

Who is the main contact? Dr Nicholas Hopkinson n.hopkinson@ic.ac.uk

## **Contact information**

**Type(s)** Scientific

**Contact name** Dr Nicholas Hopkinson

ORCID ID http://orcid.org/0000-0003-3235-0454

## **Contact details**

Royal Brompton Hospital Fulham Road London United Kingdom SW3 6NP

n.hopknson@ic.ac.uk

# Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers V1

# Study information

## Scientific Title

EDEN-EPIC: Effect of dietary nitrate supplementation on exercise performance in COPD - a randomised double-blind cross-over placebo controlled trial

#### Acronym EDEN-EPIC

#### Study objectives

The purpose of this study is to investigate the effects of an acute administration of beetroot (BR) juice versus placebo beverage ingestion on plasma NO2- levels, blood pressure, exercise tolerance and fractional oxygen extraction.

**Ethics approval required** Old ethics approval format

**Ethics approval(s)** London Bromley Research Ethics Committee, ref: 13/LO/0372

**Study design** Randomised double-blind cross-over placebo-controlled trial

**Primary study design** Interventional

**Secondary study design** Randomised cross over 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 (COPD)

**Interventions** Current interventions as of 03/06/2015: 140 ml concentrated beetroot juice or matched nitrate-depleted placebo.

Previous interventions: 70 ml concentrated beetroot juice or matched nitrate-depleted placebo.

Intervention Type Supplement

**Phase** Not Applicable

Drug/device/biological/vaccine name(s)

Dietary nitrate supplementation (beetroot juice)

## Primary outcome measure

Time to exhaustion in a fixed workload cycle ergometer test at 70% VO2max

#### Secondary outcome measures

1. Area under VO2 curve to isotime (VO2) during endurance cycle ergometry 2. Fractional oxygen extraction of quadriceps muscle as assessed by NIRS

Overall study start date 01/05/2013

**Completion date** 31/12/2014

# Eligibility

**Key inclusion criteria** Adult patients with a clinical and spirometric diagnosis of COPD, GOLD stage II-IV.

Participant type(s) Patient

**Age group** Adult

**Sex** Both

**Target number of participants** 25

#### Key exclusion criteria

Clinically unstable patients (within one month of exacerbation), significant comorbidity limiting exercise tolerance, significant renal impairment (estimated glomerular filtration rate (eGFR) <50 ml.min-1), hypotension (systolic blood pressure <100 mmHg), pregnancy, use of nitrate based medication, other reason for benefit from nitrate supplementation (ischaemic heart disease, peripheral arterial disease), use of long-term oxygen therapy.

Date of first enrolment 01/05/2013

Date of final enrolment 31/12/2014

# Locations

**Countries of recruitment** England **Study participating centre Royal Brompton Hospital** Sydney Street Chelsea London United Kingdom SW3 6NP

# Sponsor information

**Organisation** Imperial College London and Imperial College Healthcare NHS Trust (UK)

#### **Sponsor details** c/o Lucy Parker Regulatory Compliance Room 510, 5th floor Lab Block Charing Cross Hospital Fulham Palace Road London England United Kingdom W6 8RF

lucy.parker@imperial.ac.uk

#### Sponsor type

Hospital/treatment centre

#### ROR

https://ror.org/041kmwe10

# Funder(s)

Funder type Hospital/treatment centre

**Funder Name** Royal Brompton Hospital (UK)

# **Results and Publications**

## Publication and dissemination plan

Planned publication 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          | <b>Details</b><br>results | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------|---------------------------|--------------|------------|----------------|-----------------|
| Results article      |                           | 23/12/2015   |            | Yes            | No              |
| HRA research summary |                           |              | 28/06/2023 | No             | No              |