

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

Submission date 11/04/2013	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 22/04/2013	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/11/2016	Condition category 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 activities 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

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Contact information

Type(s)

Scientific

Contact name

Dr Nicholas Hopkinson

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised double-blind cross-over placebo-controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

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)

ROR

<https://ror.org/041kmwe10>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Royal Brompton Hospital (UK)

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	23/12/2015		Yes	No
HRA research summary			28/06/2023	No	No