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

Submission date
11/04/2013

Recruitment status
No longer recruiting

Registration date
22/04/2013

Overall study status
Completed

Last Edited
04/11/2016

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Contact information

Type(s)
Scientific

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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

United Kingdom

Study participating centre
Royal Brompton Hospital
Sydney Street
Chelsea
London
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Sponsor information

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

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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	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