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The effect of dietary nitrate supplementation on blood pressure and exercise capacity in people with COPD

Submission date
30/10/2019

Recruitment status
No longer recruiting

Registration date
01/11/2019

Overall study status
Completed

Last Edited
16/06/2025

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dietary nitrate supplementation, in the form of beetroot juice, has a number of potentially advantageous effects in COPD. These include improving the response to pulmonary rehabilitation programme, making muscle contraction more efficient so it uses less oxygen, and improving how far people with low oxygen levels because of their lung disease can walk. Although COPD is a lung disease, people with the condition are at a higher risk of heart disease and stroke. There is also some evidence that beetroot juice can reduce blood pressure, but studies so far have been short term. A nutritional treatment that could produce a lasting reduction in blood pressure would be appealing, especially if it also improves people's ability to exercise. The aim of this study is to investigate the prolonged treatment effects of daily beetroot juice on blood pressure in people with COPD. The researchers will also look at how far people can walk, make measurements of how well blood vessels function, and take blood samples to look at the mechanisms involved including how "sticky" platelets are. These are the cells in the blood that cause it to clot.

Who can participate?
Patients aged over 21 with COPD

What does the study involve?
Participants are randomly allocated to one of two groups. One group drinks a 70 ml beetroot juice "shot" each morning for three months. This contains nitrate, the active ingredient. The other group takes an identical juice drink which has had the nitrate removed. Which group participants are in is decided at random by a computer. Blood pressure is measured by participants at home for 4 days at the beginning and end of the study. In addition, the researchers measure how far people can walk, how well blood vessels work using a device that measures blood flow, and blood tests looking at nitrate levels and platelet function. They also collect mouth swabs to look at bacteria in the mouth to see if that changes with treatment.

What are the possible benefits and risks of participating?
If the study is positive this will help in the development of beetroot juice as a therapy for people

with COPD and other long-term conditions. Participants in the study will be helping to advance understanding of processes involved in lung disease. If the treatment is effective participants in the active arm may benefit in terms of being able to walk further. Most people report that their urine goes orange or red because of the pigments in the beetroot juice.

Where is the study run from?
Royal Brompton and Harefield NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2019 to March 2022

Who is funding the study?
Saudi Arabia Cultural Bureau in London

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
271589

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS: 271589

Study information

Scientific Title
Oral Nitrate supplementation and Blood pressure in COPD – a randomised clinical trial

Acronym
ON-BC

Study objectives
The research question is whether, in people with stable COPD, oral dietary nitrate supplementation in the form of daily 70 ml beetroot shot compared to a placebo drink of nitrate-depleted beetroot juice, reduces blood pressure and improves exercise capacity and endothelial function over a three-month period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/11/2019, London - West London & GTAC Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, UK; +44 (0)207 104 8007; 0207 104 8124; NRESCommittee.London-WestLondon@nhs.net), ref: 19/LO/1660

Study design
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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Stable COPD

Interventions
Allocation will be by computer-generated randomisation.

Active: 70 ml Beet It Stamina shot from James White Ltd (6.5 mmol Nitrate) once daily for three months
Placebo: 70 ml matched placebo shot with nitrate removed once daily for three months

Intervention Type
Supplement

Primary outcome measure
Home-monitored blood pressure measured using ambulatory blood pressure monitoring at baseline and 3 months

Secondary outcome measures
Secondary endpoints:
1. Exercise capacity measured using 6-minute walk test distance at baseline and 3 months
2. Health-related quality of life (HRQoL) assessed using the CAT score at baseline and 3 months

Exploratory endpoints measured at baseline and 3 months:
1. Endothelial function assessed using the Endopat score
2. Cardiac strain measured using Blood Brain Natriuretic Peptide levels (BNP)
3. Platelet activation measured using blood platelet-monocyte aggregates
4. Nitric oxide synthase activity assessed using plasma concentration of arginine/asymmetric dimethylarginine (ADMA)
5. Breath nitric oxide measured using fractional exhaled NO (FeNO)
6. Adequacy of supplementation measured using blood nitrate and nitrite levels
7. Nitrate metabolising oral bacteria measured using oral microbiome sampling

Overall study start date
01/03/2019

Completion date
01/03/2022

Eligibility

Key inclusion criteria
1. Adult patients (>21 years) with stable COPD GOLD I-IV
2. Established on stable pharmacotherapy for COPD
3. Systolic blood pressure >130 mmHg

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
72

Total final enrolment
81

Key exclusion criteria
1. Unable to provide informed consent
2. AECOPD in the preceding month
3. Significant comorbidity limiting exercise tolerance
4. Significant comorbidity limiting life expectancy
5. Significant renal impairment (estimated glomerular filtration rate (eGFR) <30 ml.min1)
6. Use of >3 blood pressure lowering medications
7. Change in medication in the previous month
8. Oral nitrate medication
9. Current (in the last month) use of Beet Shots

Date of first enrolment
01/12/2019

Date of final enrolment
01/06/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Brompton and Harefield NHS Foundation Trust
Fulham Rd
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Sponsor information

Organisation
Imperial College, London

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Sponsor type
University/education

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Other

Funder Name
Saudi Arabia Cultural Bureau in London

Alternative Name(s)
Royal Embassy of Saudi Arabia Cultural Bureau in London, Royal Embassy of Saudi Arabia - Cultural Bureau in London, Royal Embassy of Saudi Arabia Cultural Bureau, SACB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results will be shared through presentation at conferences and publication in peer-reviewed medical journals.

Intention to publish date
01/09/2022

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 2.0	24/06/2020	16/06/2025	No	No
Results article		01/02/2024	16/06/2025	Yes	No