

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 01/11/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/06/2025	Condition category Respiratory	<input type="checkbox"/> 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

Integrated Research Application System (IRAS)

271589

Protocol serial number

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

Primary study design

Interventional

Study design

Double-blind placebo-controlled parallel-group study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Royal Brompton and Harefield NHS Foundation Trust

Fulham Rd

London

United Kingdom

SW3 6NP

Sponsor information

Organisation

Imperial College, London

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

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?
Results article		01/02/2024	16/06/2025	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 2.0	24/06/2020	16/06/2025	No	No