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Bioavailability of beetroot compounds in older adults

Submission date
08/09/2017

Recruitment status
No longer recruiting

Registration date
24/10/2017

Overall study status
Completed

Last Edited
08/11/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
There is a growing interest in the biological activity of the root vegetable, red beetroot (Beta vulgaris rubra) and its health benefits as a functional food. Research is largely focused on the nitrate content of beetroot, which provides a natural means of increasing the availability of nitric oxide (NO). Many age-related degenerative diseases are associated with reduced NO bioavailability, such as hypertension and dementia, and beetroot is being considered as a promising treatment to slow down the progression of these diseases. In addition to nitrate, beetroot is also rich in phenolic compounds and a water-soluble group of phytochemicals called betalains. Betalains and phenolic compounds are potent antioxidants and display anti-inflammatory properties. Ageing is associated with increased oxidative damage and a diminished availability of whole-body NO. The aim of this study is to compare the bioavailability of phenolic compounds, betalain and inorganic nitrate after the ingestion of three incremental portions of whole beetroot in healthy younger and older adults.

Who can participate?
Males aged between 18 to 35 years and 60 to 75 years who are free of chronic illnesses.

What does the study involve?
Participants are randomly allocated to an order to receive one of four different treatments (100g beetroot, 200g beetroot, 300g beetroot, a dose of inorganic nitrate as a positive control). The duration of each intervention is five hours. The washout period between each phase will be one week. The difference in bioavailability of nitrate, phenolic compounds and betalains between younger and older subjects is assessed. Participants are also assessed for their blood pressure, blood flow, exhaled nitric oxide and tolerability to the interventions.

What are the possible benefits and risks of participating?
Participants may benefit from monetary reimbursement and from undergoing a body composition analysis. There are minor risks. Beetroot consumption can cause beeturia, discolouration of the urine, which is harmless and perfectly normal. Blood sampling can cause some minor bruising.

Where is the study run from?
Royal Victoria Infirmary (UK)

When is the study starting and how long is it expected to run for?
June 2016 to December 2017

Who is funding the study?
1. Gs Fresh Ltd (UK)
2. Newcastle University (UK)

Who is the main contact?
Miss Tess Capper
Professor Emma Stevenson

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
7985

Study information

Scientific Title
Bioavailability of phenolic compounds, betalain and inorganic nitrate following incremental portions of whole beetroot in older and younger adults

Acronym
Beetroot study

Study objectives
We hypothesise that, due to possible changes in the oral bacteria and microbiome of older adults, the bioavailability of nitrate, betalains and phenolic compounds from whole beetroot will be less in older adults than in younger adults. We do, however, predict a trend towards a dose response to incremental portions, with higher amounts of beetroot causing an increased bioavailability of the compounds contained within it in both populations, despite an inter-individual variation. Due to a reduction in whole-body NO, it is predicted that the positive effect on vascular function associated with nitrate will be reduced in the older population. We expect that the response to the potassium nitrate will be higher than that of the beetroot, eliciting greater reductions in blood pressure and improved blood flow. We hypothesise that the vascular response to the beetroot will be greater with higher quantities in both populations

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridge Central NRES Committee, East of England, 26/09/2016, ref: 16/EE/0376

Study design
Acute 4-arm randomized crossover intervention study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Age-related degenerative diseases

Interventions
Participants are randomised using a Latin-Square method. Participants are allocated in a random order to receive the four interventions.

The four interventions include:
1. 100 g whole pre-cooked beetroot

2. 200 g whole pre-cooked beetroot
3. 300 g whole pre-cooked beetroot
4. 200 ml potassium nitrate solution.

Participants are asked to consume the supplement within 15 minutes after baseline testing, and measurements will be taken for 5 hours post-supplementation. The duration of each intervention will be 5 hours. The washout period between each phase will be one week.

Intervention Type
Supplement

Primary outcome(s)
Differences in bioavailability of nitrate between incremental doses of beetroot and compared to a standard dose of potassium nitrate at 5 hours

Key secondary outcome(s))
1. Differences in changes in blood pressure following each dose of nitrate supplementation and compared to a standard dose of potassium nitrate at 5 hours
2. Differences in changes in endothelial function following each dose of nitrate supplementation and compared to a standard dose of potassium nitrate at 5 hours
3. Differences in changes in exhaled nitric oxide following each dose of nitrate supplementation and compared to a standard dose of potassium nitrate at 5 hours
4. Differences in bioavailability of betalains and phenolic compounds between incremental doses of beetroot and compared to a standard dose of potassium nitrate at 5 hours

Completion date
22/12/2017

Eligibility

Key inclusion criteria
1. Non-obese
2. Non-smoker
3. Males aged between 18 and 35 or 60 and 75 years
4. Free of chronic illness

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
75 years

Sex
Male

Total final enrolment
24

Key exclusion criteria
1. Vegetarianism
2. High blood pressure
3. Active cancer and any diagnosis of malignant cancer in the last 5 years
4. Diagnosis of chronic and acute metabolic and inflammatory conditions interfering with the study outcome
5. Medications that may have an effect on NO production
6. Hormonal therapies, statins and psychiatric drugs if dose started/changed in previous 3 months
7. Haematological disorders
8. History of repetitive gastric reflux
9. Excessive alcohol intake
10. Allergy or intolerance to the intervention food
11. Under the age of 18
12. Smoker

Date of first enrolment
01/12/2016

Date of final enrolment
17/11/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Victoria Infirmary
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Industry

Funder Name
Gs Fresh Ltd

Funder Name
Newcastle University

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available due to not being able to be made available online.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/01/2022	08/11/2023	Yes	No
Basic results		16/01/2020	20/01/2020	No	No
Basic results		06/02/2020	06/02/2020	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version v4.0	24/10/2016	01/04/2019	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes