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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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### Type(s)
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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
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

### Secondary study design
Randomised cross over trial

### Study setting(s)
Hospital

### Study type(s)
Other

### Participant information sheet
See study outputs table

### 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 measure
Differences in bioavailability of nitrate between incremental doses of beetroot and compared to a standard dose of potassium nitrate at 5 hours

### Secondary outcome measures
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

### Overall study start date
01/06/2016

### 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

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
75 Years

### Sex
Male

### Target number of participants
30

### 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
England

United Kingdom

### Study participating centre

**Royal Victoria Infirmary**
Newcastle upon Tyne
United Kingdom
NE1 4LP

# Sponsor information

**Organisation**
Newcastle upon Tyne Hospitals NHS Foundation Trust

**Sponsor details**
Level 1, Regent Point
Regent Farm Road
Gosforth
Newcastle upon Tyne
England
United Kingdom
NE3 3HD

**Sponsor type**
Research organisation

**Website**
http://www.newcastlejro.org.uk/

**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

### Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

### Intention to publish date
31/12/2020

### 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? |
|---|---|---|---|---|---|
| Participant information sheet | version v4.0 | 24/10/2016 | 01/04/2019 | No | Yes |
| 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 |
| Results article | | 11/01/2022 | 08/11/2023 | Yes | No |