

# Effects of increased consumption of leaf and stalk vegetables and beetroot on cardiovascular function: VegBP project

<b>Submission date</b> 27/10/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/10/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/10/2017	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

8420

# Study information

## Scientific Title

Effects of increased consumption of leaf and stalk vegetables and beetroot on cardiovascular function: VegBP project

## Acronym

VegBP

## Study objectives

Cardiovascular diseases (CVD) are the principal cause of death and morbidity in the UK and the risk of CVD is directly related to increases in blood pressure. Therefore, it is essential to maintain blood pressure within an optimal range in order to reduce CVD risk. Previous epidemiological studies suggested that increased fruits and vegetables intake may reduce blood pressure, although the specific type(s) of fruits and/or vegetables which are responsible for this effect is not known. In particular, green leafy or other salad vegetables (such as beetroot) high in nitrates may be responsible, since nitric oxide formed naturally in the body from these nitrates play an important role in maintaining the function of blood vessels.

Therefore, in the present study we will investigate effects of increased consumption of green-leafy or other salad vegetables on blood pressure in comparison with other vegetables such as carrots, broccoli (low in nitrates). Volunteers recruited will be instructed to avoid all vegetables that are high in nitrates from a list provided for the first eight weeks of the study. After this 'washout' period, volunteers will be randomly assigned to three different groups. Each group will be asked to have 100 g/day of specific vegetables in addition to their normal diet for a further 16 weeks. Group 1 will have green-leafy or other salad vegetables, Group 2 will have other vegetables (low in nitrates) and Group 3 will have half of each type of vegetables as consumed by Groups 1 and 2.

Using non-invasive devices, resting blood pressure, 24 hour blood pressure and flow in blood vessels (using ultrasound) in the arm will be measured at the start of the study and after every 8 weeks throughout the study. Blood and saliva samples will also be collected during these occasions to monitor biochemical changes related to specific vegetable intake and monitor compliance to the study protocol.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

MREC approved on 22/06/2010, ref: 10/H0908/27

## Study design

Single-centre randomised interventional prevention trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

**Study setting(s)**

GP practice

**Study type(s)**

Prevention

**Participant information sheet****Health condition(s) or problem(s) studied**

Topic: Primary Care Research Network for England, Cardiovascular, Generic Health Relevance and Cross Cutting Themes; Subtopic: Not Assigned, Cardiovascular (all Subtopics), Generic Health Relevance (all Subtopics); Disease: Cardiovascular, All Diseases, Public Health Research

**Interventions**

Vegetable Group 1: Additional consumption of 100 g per day of vegetables from mixed leaf lettuce, beetroot and spinach for a 16-week intervention period

Vegetable Group 2: Additional consumption of 100 g per day of vegetables from yellow tomatoes, peas and sweetcorn for a 16-week intervention period

Vegetable Group 3: Additional consumption of 50 g per day of vegetables from mixed leaf lettuce, beetroot and spinach and 50 g per day of vegetables from peas, sweetcorn and yellow tomatoes for a 16-week intervention period

Follow up length: 6 months

Study entry: single randomisation only

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Seated Blood Pressure, measured twice within 1 week every 8 weeks over a 24 week period (8 times in total).

**Secondary outcome measures**

1. 24-hour ambulatory blood pressure, measured once every 8 weeks over a 24-week period (4 measurements in total)
2. C-reactive protein (CRP) and biochemical markers of endothelial function, measured twice within 1 week every 8 weeks over a 24-week period (8 times in total)
3. Fasting blood glucose, measured once every 8 weeks over a 24-week period (4 measurements in total)
4. Fasting blood lipid profile, measured twice within 1 week every 8 weeks over a 24-week period (8 measurements in total)
5. Flow mediated dilation, measured once every 8 weeks over a 24-week period (4 measurements in total)
6. Plasma carotenoids and polyphenols, measured twice within 1 week every 8 weeks over a 24-week period (8 times in total)
7. Weight and body composition, measured once every 8 weeks over a 24-week period (4 times in total)

**Overall study start date**

15/07/2010

**Completion date**

17/12/2012

## Eligibility

**Key inclusion criteria**

1. Male or female subjects aged 40 - 75 years
2. Systolic blood pressure in the range 130 - 150 mmHg

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

Planned sample size: 225; UK sample size: 225

**Key exclusion criteria**

1. Body mass index (BMI) greater than 30 kg/m<sup>2</sup>
2. Habitual consumption of green leafy vegetables higher than the population mean (= exclusion of the highest quartile, since the distribution of intake is highly skewed)
3. Recent or current serious disease (cancer, cardiovascular disease [CVD], etc.)
4. History of persistent gastric reflux or H. pylori infection
5. Allergies or intolerances to intervention foods
6. Planning to change dietary habits, increase physical activity, change body weight or move away from the study locality during the time of the study
7. Smokers
8. Taking antihypertensives for elevated blood pressure
9. Taking prescribed nitrates for angina or heart failure
10. Taking statins
11. History of substance abuse or alcoholism

**Date of first enrolment**

15/07/2010

**Date of final enrolment**

17/12/2012

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Newcastle University**  
Newcastle Upon Tyne  
United Kingdom  
NE1 7RU

## **Sponsor information**

**Organisation**

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

**Sponsor details**

Midwifery Research Department  
Leazes Wing  
Queen Victoria Road  
Newcastle upon Tyne  
England  
United Kingdom  
NE1 4LP

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.newcastle-hospitals.org.uk/>

**ROR**

<https://ror.org/05p40t847>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Food Standards Agency (FSA) (UK) (ref: N02046)

**Alternative Name(s)**

The Food Standards Agency, FSA

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration