

A dose response study of the effects of increased fruit and vegetables intake on vascular function

Submission date 25/08/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/01/2011	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N2030

Study information

Scientific Title

Acronym

DRFRUITNVEG

Study objectives

This study will address the hypothesis that:

1. An increase in potassium intake as fruit and vegetables by 20 to 40 mmol/day will lower blood pressure and that beyond this threshold level there will be no further reduction in blood pressure
2. An increase in fruit and vegetable intake will have beneficial effects on arterial compliance and endothelial function
3. That the effect is attributable to an increase in potassium intake

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Elevated blood pressure

Interventions

The dietary intervention will compare three levels of fruit and vegetable intake to supply additional potassium intakes of 0, 20 and 40 mmol/day of potassium versus an additional 40 mmol/day provided as a supplement.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Fruit and vegetables

Primary outcome measure

Blood Pressure

Secondary outcome measures

1. Pulse Wave Velocity
2. Endothelial Function (flow mediated dilatation)
3. Biochemical indices of endothelial function

Overall study start date

01/10/2004

Completion date

30/09/2006

Eligibility**Key inclusion criteria**

Subjects will be male or female, non-smoking and aged between 22-65 years. A principal aim is to identify and recruit subjects with moderate elevation of Blood Pressure (BP). Eligible subjects will have diastolic more than 80 mmHg and less than 100 mmHg and a systolic BP of less than 160 mmHg.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

48

Key exclusion criteria

1. Current smokers
2. A reported history of myocardial infarction or cancer
3. Diabetes mellitus (fasting plasma glucose more than 7 mmol/l)
4. Recent use of oral hypolipidaemic therapy, systemic corticosteroids, androgens, phenytoin, erythromycin or thyroid hormones
5. Current use of antihypertensive medication
6. Those receiving drugs for regulating haemostasis but excluding aspirin or who have been exposed to any investigational agent within 30 days of the study
7. Chronic coronary, renal or bowel disease or history of cholestatic liver disease or pancreatitis

8. Presence of gastrointestinal disorder or use of a drug, which is likely to alter gastrointestinal motility or nutrient absorption
9. History of substance abuse or alcoholism
10. Currently pregnant, planning pregnancy, or having had a baby in the last 12 months
11. Allergy or intolerance to intervention foods
12. Unwilling to follow the protocol and/or give informed consent
13. Unwilling to refrain from use of dietary supplements
14. Weight loss at more than 3 kg in preceding two months
15. Alcohol intake not exceeding a moderate intake of (less than 24 - 36 g/day)
16. Body Mass Index more than 20 and less than 35 kg/m²
17. Subjects with a blood pressure and other risk factors that make them eligible for drug treatment of raised blood pressure according to the UK guidelines of the British Hypertension Society

Date of first enrolment

01/10/2004

Date of final enrolment

30/09/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Nutritional Sciences Research Division

London

United Kingdom

SE1 9NH

Sponsor information

Organisation

Food Standards Agency (UK)

Sponsor details

Aviation House

125 Kingsway

London

United Kingdom

WC2B 6NH

Sponsor type

Government

Website

<http://www.food.gov.uk>

ROR

<https://ror.org/05p20a626>

Funder(s)

Funder type

Government

Funder Name

Food Standards Agency Project (reference number: N02030)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2010		Yes	No