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

Submission date	Recruitment status	Prospectively registered		
25/08/2005	No longer recruiting	Protocol		
Registration date	Overall study status	Statistical analysis plan		
09/09/2005	Completed	[X] Results		
Last Edited 06/01/2011	Condition category Circulatory System	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number 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

Study type(s)

Quality of life

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(s)

Blood Pressure

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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/m^2
- 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

United Kingdom

England

Study participating centre Nutritional Sciences Research Division

London United Kingdom SE1 9NH

Sponsor information

Organisation

Food Standards Agency (UK)

ROR

https://ror.org/05p20a626

Funder(s)

Funder type

Government

Funder Name

Food Standards Agency Project (reference number: N02030)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot 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