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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/09/2005	**Overall study status** Completed	
Last Edited 06/01/2011	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 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