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Flavonoids Kinetics Study

Submission date 10/03/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2011	**Overall study status** Completed	
Last Edited 19/05/2014	**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

Study information

Scientific Title
The effect of an acute ingestion of a flavonoid-rich fruit and vegetable puree based drink on vasodilation and other risk factors of cardiovascular disease in healthy individuals

Acronym
FlaKS

Study objectives

Consumption of a flavonoid-rich fruit and vegetable puree-based drink will acutely increase endothelium-dependent vasodilation, plasma antioxidant status and plasma and urinary concentrations of phytochemical metabolites.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Reading Research Ethics Committee ref: No. 05/06

Primary study design
Interventional

Study design
Randomised controlled single-blind intervention study

Study type(s)
Screening

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions
Fruit and vegetable puree-based drink (Vie shot, Unilever Bestfoods, Germany) and a sugar-matched fruit-flavoured cordial as the control

The intervention food was 400 mL of either flavonoid-rich fruit and vegetable puree-based drink (Apple, Carrot and Strawberry Vie, Unilever Bestfoods) or a low-flavonoid fruit-flavoured sugar-matched control drink. The participants randomly consumed 400 mL one of the drinks on the morning of the study day. They remained in the Human Nutrition Unit for 8 hours post-ingestion and then returned the following morning to return an overnight urine collection and to give a blood sample. After a 4-week washout period they repeated the procedure with the other intervention drink.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Vasodilation assessed using laser doppler imaging with iontophoresis
2. Vascular measurements were determined within 2 months of the end of the study

Key secondary outcome(s)
The antioxidant status was measured by:
1. The ferric reducing antioxidant power (FRAP) assay
2. The oxygen radical absorbance capacity (ORAC) assay
3. By measuring the susceptibility of low density lipoprotein (LDL) to oxidation by a copper catalyst

Completion date
20/12/2006

Eligibility

Key inclusion criteria
1. Healthy individuals
2. Male or female
3. Aged 20-50 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Suffering from any form of known liver disease, diabetes mellitus or a myocardial infarction
2. Suffering from gall bladder problems or abnormalities of fat metabolism
3. On a weight reducing dietary regimen or taking any dietary supplements, including dietary fatty acids
4. Exercising more than three times a week for more than 20 minutes each session
5. Consuming more than 15 units of alcohol per week

Date of first enrolment
01/05/2006

Date of final enrolment
20/12/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Department of Food and Nutritional Sciences
Reading
United Kingdom
RG6 6AP

Sponsor information

Organisation
University of Reading (UK)

ROR
https://ror.org/05v62cm79

Funder(s)

Funder type
University/education

Funder Name
University of Reading Research Endowment Trust Fund (UK)

Funder Name
Unilever Bestfoods (Germany)

Funder Name
The Royal Thai Government (Ministry of Science and Technology)

Funder Name
Chiangmai University (Thailand)

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	01/05/2009		Yes	No