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# Flavonoids Kinetics Study

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

**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**
N/A

## 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

## Study design
Randomised controlled single-blind intervention study

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Other

## Study type(s)
Screening

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## 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 measure
1. Vasodilation assessed using laser doppler imaging with iontophoresis
2. Vascular measurements were determined within 2 months of the end of the study

### Secondary outcome measures
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

### Overall study start date
01/05/2006

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
25

### 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**
England

United Kingdom

**Study participating centre**
**Department of Food and Nutritional Sciences**
Reading
United Kingdom
RG6 6AP

# Sponsor information

**Organisation**
University of Reading (UK)

**Sponsor details**
Whiteknights
PO Box 217
Reading
England
United Kingdom
RG6 6AP

**Sponsor type**
University/education

**Website**
http://www.reading.ac.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

**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 | 01/05/2009 | | Yes | No |