

FLAVonoids: University of Reading Study

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| Submission date 12/11/2007 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 11/12/2007 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 13/01/2015 | 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

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N02R0001

Study information

Scientific Title

Impact of increasing doses of flavonoid-rich and flavonoid-poor fruit and vegetables on cardiovascular risk factors in an at risk group

Acronym

FLAVURS

Study objectives

To determine the impact of different amounts and types (flavonoid-rich versus flavonoid-poor) of fruit and vegetables on heart disease risk factors in an 'at risk' group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Isle of Wight, Portsmouth and South East Hampshire Research Ethics Committee on 6th November 2007 (REC no.: 07/H0501/81).

Study design

A single-blind, single-centre, randomised, controlled dietary intervention study with three parallel treatment arms (one control and two intervention groups)

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

Cardiovascular disease

Interventions

After a three week run-in period following a habitual (low fruit and vegetable) diet, 180 participants, selected on the basis of their increased risk of developing cardiovascular disease, will be randomly assigned to either the habitual diet (control) or one of two intervention groups, which involves the increased intake of flavonoid-rich or flavonoid-poor fruits and vegetables. In both intervention groups, participants will be asked to sequentially increase their fruit and vegetable intake by 2, 4 and 6 portions, with a 6-week duration for each dose increase. The

intervention phase will last for 18-weeks. Due to the duration of the study, a parallel design is adopted to minimise burden on the participants. The control group is necessary to control for the impact of study participation and seasonal effects on the outcomes of the study.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Each subject has to attend four intervention visits in total for the study. The following primary outcome measures will be taken at each visit:

1. Changes in endothelial function measured by vascular reactivity and arterial stiffness using Laser Doppler Imaging with iontophoresis and Pulse Wave Analysis measurement respectively
2. Plasma biomarkers of endothelial function (e.g. nitric oxide, Vascular Cell Adhesion Molecule [VCAM], Intercellular Adhesion Molecule [ICAM], E-selectin, von Willebrand factor, microalbumin) - fasting bloods will be taken at each visit to measure these outcomes

Secondary outcome measures

1. Fasting bloods will be taken during each intervention visit to measure the following outcomes:
 - 1.1. Fasting lipids (total, Low Density Lipoprotein [LDL] cholesterol, HDL cholesterol, triglycerides and non-esterified fatty acids)
 - 1.2. Indices of insulin resistance
 - 1.3. Haemostatic factors (Plasminogen Activator Inhibitor 1 [PAI-1], fibrinogen)
 - 1.4. Inflammatory biomarkers (C-Reactive Protein [CRP], Tumour Necrotising Factor [TNF]-alpha and Interleukin-6 [IL6])
2. The following will be measured during the 6-week intervention periods between visits:
 - 2.1. 24-hour ambulatory blood pressure
 - 2.2. Dietary intake assessed by 24 hour dietary recalls and biomarkers of fruit and vegetable intake (24 hour urinary flavonoid metabolites, urinary potassium, plasma ascorbic acid)
3. Faecal samples will be collected at each intervention visit to perform quantitative and qualitative analysis of faecal microflora and estimation of faecal water genotoxicity and mucosal integrity
4. Changes in cognitive performance will be measured during each intervention visits using computer tests

Overall study start date

19/11/2007

Completion date

30/10/2009

Eligibility

Key inclusion criteria

1. Men and women between the ages of 30 - 70 years
2. At above average risk of developing heart disease
3. Meet one or more of the following criteria:
 - 3.1. Overweight
 - 3.2. High total cholesterol (but not on medication)

3.3. Low High Density Lipoprotein (HDL) cholesterol

3.4. High blood pressure (but not on medication)

3.5. Cigarette smoker

For the specific range of inclusion for each risk factor, we have come up with a scoring system, adapted mainly from the Framingham study. Volunteers who have an above average risk of developing heart disease (RR 1.5) would be included in the study. Volunteers who have risk factor/s at a very high risk level would be excluded. Participants should also have a low intake of fruit and vegetable (i.e. less than or equal to 3 portions per day).

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

180

Key exclusion criteria

People:

1. Who have diabetes, heart disease (previous stroke/myocardial infarction), renal or bowel or liver diseases and hormone abnormalities
2. On drug treatment for hyperlipidemia, hypertension, inflammation or hypercoagulation
3. Taking dietary supplements (e.g. vitamins and minerals, fish oils)
4. Who drink more than 15 units of alcohol per week
5. Who are pregnant, lactating or if of reproductive age and not using a reliable form of contraception (including abstinence)
6. Who are regularly undertaking vigorous exercise or fitness training
7. Who are on a weight-reducing regime
8. Who consume over 3 portions of fruit and vegetables per day

Date of first enrolment

19/11/2007

Date of final enrolment

30/10/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Hugh Sinclair Human Nutrition Unit
Reading
United Kingdom
RG6 6AP

Sponsor information

Organisation

Foods Standards Agency (UK)

Sponsor details

Aviation House
125 Kingsway
London
United Kingdom
WC2 6NH

Sponsor type

Government

Website

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

ROR

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

Funder(s)

Funder type

Government

Funder Name

Foods Standards Agency (UK) (ref: N02R0001)

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 | 01/02/2013 | | Yes | No |
| Results article | results | 01/03/2014 | | Yes | No |
| Results article | results | 01/11/2014 | | Yes | No |