

Effects of chronic consumption of cocoa flavonoids on vascular function

Submission date 26/07/2013	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/08/2013	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 24/10/2019	Condition category Circulatory System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

This is a study to investigate the effects of long-term cocoa intake on the cardiovascular health of post-menopausal women as they are known to be at greater risk of cardiovascular disease. Our goal is to investigate if drinking cocoa high in antioxidant compounds called flavonoids will improve your cardiovascular health.

Who can participate?

Post-menopausal women aged between 49 and 65 years.

What does the study involve?

Initially we will ask you questions about your medical history, measure your weight, height, blood pressure, waist and hip circumference. We take a small blood sample to ascertain that your blood chemistry is normal. Providing the blood tests are normal you will then be invited to take part in the study and attend the hospital on a total of four occasions - at the beginning and end of each 6-week period. You will be required to give blood and urine samples and have your arteries scanned at the beginning and end of each 6-week period. You will be randomly allocated to receive either specially made cocoa powder or a dummy (placebo) cocoa powder dissolved in water daily for 6 weeks. There will then be a 4-week break where you do not have to consume any cocoa. After this, you will receive the other cocoa powder to drink daily for 6 weeks.

What are the possible benefits and risks of participating?

There could be benefits from drinking the high antioxidant cocoa. There is a small risk of bruising from giving a blood sample. The scan of the arteries requires placing a tablet (glyceryl trinitrite) under your tongue for 5 minutes before the scan and this may cause some tingling, discomfort or pain.

Where is the study run from?

The study is run from King's College London in collaboration with St Thomas Hospital (UK).

When is the study starting and how long is it expected to run for?

August 2006 to February 2007

Who is funding the study?
King's College London (UK) and the cocoa was manufactured and supplied by Mars Inc

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
05/06-158

Study information

Scientific Title
An investigation into the effects of chronic consumption of cocoa flavonoids on vascular function: a randomised controlled trial

Study objectives
Cocoa flavonoids lower blood pressure and improve endothelial function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
King's College London Research Ethics Committee, 04/08/2006

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Screening

Health condition(s) or problem(s) studied

Cardiovascular disease

Interventions

Subjects were supplied with packets of cocoa powder. They were instructed to take two packets daily for two 6 week periods (dissolved in water) with a break inbetween (minimum of 4 weeks break). Each pack contained 20g of cocoa. The placebo product contained 16 mg of flavonols per packet and the flavonol rich product contained approximately 330 mg of flavonols per packet. Subjects consumed twice this amount per day as they had two packets per day. There was no follow up once they had finished the study (the two 6 week interventions).

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Blood pressure

The outcome measures were taken at the beginning and end of each intervention period.

Key secondary outcome(s)

Arterial stiffness, flow mediated dilatation, plasma ICAM-1, VCAM-1, C-reactive protein, P-selectin, 8-isoprostane F2 α , lipids and urinary 8-isoprostane F2

Completion date

28/02/2007

Eligibility

Key inclusion criteria

Non-smoking postmenopausal women aged between 48 and 65 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Current smokers were excluded due to confounding influences of smoking on measurement of endothelial function
2. A reported history of myocardial infarction, angina, venous thrombosis, stroke, diabetes (fasting plasma glucose > 7mmol/L) or invasive cancer in the last five years
3. Recent use of oral hypolipidaemic therapy (in the last three months)
4. Current use of antihypertensive medication
5. Those receiving drugs for regulating haemostasis but excluding aspirin or who have been exposed to any investigational agent within 30 days of the study
6. Presence of gastrointestinal disorder or use of a drug, which is likely to alter gastrointestinal motility or nutrient absorption
7. Alcohol intake exceeding a moderate intake (>28 units per week)
8. Body Mass Index between <20 or >35 kg/m²
9. Blood pressure systolic >160mm Hg or diastolic >100 mm Hg
10. Fasting blood cholesterol >7.8 mmol/l
11. Fasting plasma triacylglycerol concentrations > 3 mmol/l
12. Estimated cardiovascular risk of greater than 20% over the next 10 years using the Framingham algorithm
13. Subjects unable to tolerate chocolate products
14. Dietary supplements other than vitamin and mineral supplement or fish oil (not exceeding 0.45g long chain n-3 fatty acids/d)

Date of first enrolment

24/08/2006

Date of final enrolment

28/02/2007

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

150 Stamford Street

London

United Kingdom

SE1 9NH

Sponsor information

Organisation

Kings College London (UK)

ROR

<https://ror.org/0220mzb33>

Funder(s)**Funder type**

University/education

Funder Name

King's College London

Alternative Name(s)

King's, Collegium Regium apud Londinenses, Collegium Regale Londinense, Collegium Regale Londiniense, KCL

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Funder Name

Mars

Alternative Name(s)

Mars Incorporated, Mars, Incorporated

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary