ISRCTN32888088 https://doi.org/10.1186/ISRCTN32888088

Effects of chronic consumption of cocoa flavonoids on vascular function

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

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

Secondary outcome measures
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

Overall study start date
24/08/2006

Completion date
28/02/2007

Eligibility

Key inclusion criteria
Non-smoking postmenopausal women aged between 48 and 65 years

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
16

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 triacyglycerol 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
England

United Kingdom

Study participating centre
150 Stamford Street
London
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Sponsor information

Organisation
Kings College London (UK)

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Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
University/education

Funder Name
King’s College London

Alternative Name(s)
Collegium Regale Londiniense, King's, 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

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