Effect of food matrix on bioavailability of cocoa polyphenols

Published: 01-07-2008
Last updated: 07-05-2024

To study the bioavailability of cocoa polyphenols incorporated into a food product. The food product is a soy-based drink to which cocoa powder is added. To compare the bioavailability of cocoa polyphenols incorporated either into a soy drink or...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON31523

Source
ToetsingOnline

Brief title
Cocoa bioavailability

Condition

- Other condition

Synonym
high blood pressure, Hypertension

Health condition

De uitkomsten van deze studie gaan gebruikt worden voor een geplande vervolgstudie naar het effect van cacaopolyfenolen op de bloeddruk. Deze biobeschikbaarheidsstudie heeft zelf niet op een aandoening betrekking.

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Unilever,Unilever Food and Health Research Institute

Intervention

Keyword: Bioavailability, Cocoa, Food matrix, Polyphenols

Outcome measures

Primary outcome

Two types of body fluids will be collected, i.e. urine and blood. We will focus in plasma on the kinetic profiles of catechins by using HPLC and LC-MS techniques. The 24-hour urine samples contain accumulated metabolites in relatively high concentrations. We will measure several phenolic metabolites by using GC-MS.

Secondary outcome

The effects of cocoa polyphenols on the plasma lipid profile and glucose will be evaluated. Total cholesterol, LDL-C, HDL-C, TG and glucose will be measured by quantitive clinical chemical analysis using the Hitachi 912 analyzer.

Study description

Background summary

The bioavailability of particularly intact complex polyphenols has been the subject of debate for years now. A recently published study with black tea consumed with and without milk (**English way of drinking tea**) suggested that even the food matrix in which the polyphenols are consumed may affect bioavailability.

Study objective

To study the bioavailability of cocoa polyphenols incorporated into a food product. The food product is a soy-based drink to which cocoa powder is added.
To compare the bioavailability of cocoa polyphenols incorporated either into a soy drink or yoghurt drink and consumed during a standardised meal
To evaluate the effects of cocoa polyphenols on the plasma lipid profile and glucose.

Study design

Placebo controlled randomised cross-over study with five treatments. The total duration of the study is 3 weeks.

Intervention

On 5 days in the 3 weeks trial period the volunteers will randomly consume one of five soy or yoghurt based test drinks with or without cocoa extract. At the end of the study the volunteers will have consumed one of each test drink.

Study burden and risks

The general health of the volunteers will be determined by means of the selection questionnaire at the screening visit, a physical examination and by taking urine and blood samples. After volunteers are included, the volunteers will be asked to come for 5 visits of 9 hours. Each visit starts with placing an iv drip, which will be used to draw blood from. After drawing the first blood sample the volunteers are asked to consume one test drink and are asked to start collecting 24-hour urine. 8 more blood samples are drawn over the day. The next day the urine collection vials are handed in. At each visit the subjects will be asked to complete a questionnaire about their health and lifestyle.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam

Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Male
Age 18-70 years
Body Mass Index (BMI) 19-30 kg/m2
Reported alcohol consumption < 28 alcohol units/week
Willing to refrain from food and foodsupplements that contain polyphenols during the study
Informed consent signed
Prepared to consume test products for the duration of the study and comply with the background diet.
Prepared to donate blood samples during the study, and prepared to fill out questionnaires.
Urine parameters within normal reference range as judged by the research physician
Clinical chemical parameters within the normal reference range as judged by research physician
Accessible veins on both arms as determined by research physician

Exclusion criteria

Females
Being an employee of the AMC
A recorded history or current metabolic diseases, chronic gastrointestinal disorders, cardiovascular or renal disease
Currently on a medically prescribed diet, or slimming diet
Reported intense sporting activities > 10 hours/week
Subjects who receive medical treatment
Any surgery in the past 6 months
Use of systemic antibiotics in the past 3 months

Recent blood donation i.e. 1 month prior to the study and no planned blood donation during the study period
Known intolerance or allergy to cocoa, soy or lactose
Reported weight change ± 10% the past 6 months
Participation in another biomedical study 3 months before the start or during the study
The habit of smoking during the past year
Consuming meat and/or fish less than twice a week
Participation in night shift work

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2008
Enrollment:	12
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL21194.018.08