Pharmacokinetic study to assess the bioavailability of the cocoa flavanols catechin and epicatechin from different matrices.

Published: 20-05-2011
Last updated: 28-04-2024

The objective of the study is to assess the impact of the physical form of five different cocoa matrices on the bioavailability of the monomeric flavan-3-ols. Assessment and evaluation will be done by comparing the kinetics of the main study…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON35796

Source
ToetsingOnline

Brief title
Bioavailabilty of cocoa flavanols from different matrces

Condition

- Cardiac disorders, signs and symptoms NEC
- Vascular injuries

Synonym
cardiovascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Callebaut NV
Source(s) of monetary or material Support: ProDigest;spin-off van Unitersiteit Gent/ Callebaut NV

Intervention

Keyword: catechin, cocoa, epicatechin, flavanols

Outcome measures

Primary outcome

Area under the blood concetration - time curve (AUC).

Secondary outcome

Maximal blood concentration (Cmax) and time to maximal blood concentration

(Tmax).

Study description

Background summary

Cocoa and chocolate products have generated significant interest due to their association with various health-protective and therapeutic activities. Cocoa and chocolate are rich sources of flavan-3-ols, which are present in monomeric and polymeric forms. Although the concentration of specific flavan-3-ol species in cocoa and chocolate varies greatly depending on the raw material, the type of processing, and the nature of the finished product, monomers are one of the predominant forms present. Major monomeric flavan-3-ols present in cocoa and chocolate include (+)-catechin and (-)-catechin and (-)-epicatechin. Many of the proposed health-protective activities associated with the consumption of cocoa and chocolate have been attributed to such flavan-3-ols, including monomers. Interest in these activities has resulted in the need to better understand the bioavailability of flavan-3-ol monomers, especially when consumed at levels reasonably found in commercial cocoa matrices. Due to the fact that the net absorption and resulting circulating levels of flavan-3-ols are regarded to be generally low, designing matrices to optimize the flavan-3-ol bioavailability resulting from cocoa consumption could prove to be an important strategy for maximizing the in vivo health benefits from cocoa

products.

Study objective

The objective of the study is to assess the impact of the physical form of five different cocoa matrices on the bioavailability of the monomeric flavan-3-ols. Assessment and evaluation will be done by comparing the kinetics of the main study parameter: catechin and epicatechin in the serum following a single oral consumption of the cocoa formulation.

Study design

Blinded, randomized, placebo-controlled cross-over studie with 6 subjects.

Intervention

Five single doses of a cocoa products in randomised order with a minimal 5-day interval. Four of those cocoa products contain a high level of flavenols and are commercially available. One product is nog commercially available and is only made for clinical trials. This placebo product has exactly the same recipe as the other product, but uses the lowest level of flavenols as possible.

Study burden and risks

The risk for the volunteers is considerd negligible. The study comprises around 5 weeks and in total 31 venous blood samples are taken (a total of 515 mL blood) using 1 venapunction and 5 peripheral intravenous catheters. The trial comprises of 6 site visits. Vounteers will not benefit directly from participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Adults between 20 and 45 years old
-Non*smoking individuals
-Capable and willing to sign the Informed Consent Form at voluntary basis
-Considered healthy based on their medical history as questioned by the investigator during an interview and a general physical examination by the investigator
-Female volunteers do not intend to become pregnant prior to or during the study and using adequate contraception

Exclusion criteria

-Clinically significant abnormal liver biochemistry
-Clinically significant abnormal serum creatinin
-Abnormal body mass index
-Use of concomitant medications or supplements
-Blood donation during the last 4 weeks prior to the first dosing till 4 weeks after the last dosing

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2011
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	20-05-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL36388.068.11