cardiovascular health effects of flavanol rich chocolate

Published: 22-11-2010
Last updated: 04-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular injuries
Study type	Interventional

Summary

ID

NL-OMON34562

Source
ToetsingOnline

Brief title
CHOC

Condition

- Vascular injuries

Synonym
endothelial dysfunction, vascular health

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: TI Food and Nutrition

Intervention

Keyword: chocolate, endothelial, flavanol, vascular

Outcome measures

Primary outcome

Vascular measurements: Flow-mediated dilatation (FMD), Pulse Wave Analysis

(PWA) of the radial artery and Blood pressure

Secondary outcome

Blood hematocrite and complete blood count

Plasma epicatechins

Peripheral blood mononuclear cell (PBMC) protein and gene expression profiles

Cell surface activation markers of white blood cells

Plasma markers of endothelial function, inflammation and oxidative stress

Urine markers of oxidative stress and kidney function

Study description

Background summary

Endothelial dysfunction (ED) is a hallmark for the initial stage of vascular dysfunction and has been associated with diet-related disorders such as cardiovascular disease. Oxidative stress can be regarded as a common dominator in ED as it can decrease the bioavailability of nitric oxide (NO), a major mediator in relaxation of vascular smooth muscles. Cacao flavanols may have a positive effect on endothelial cells, by increase in bioavailability of NO. In the current study we aim to investigate the effects of flavanol rich chocolate on vascular function, inflammation, oxidative stress and biomarkers of endothelial dysfunction.

Study objective

The primary objectives are formulated to investigate the effect of chocolate flavanols on vascular function, inflammation, oxidative stress and markers of endothelial function. The effects of both acute consumption and prolonged consumption will be studied. Our secondary objectives are to investigate if daily intake of chocolate flavanols for 4 weeks will improve the response to a high fat/high energy challenge.

Study design

The CHOC-study will consist of two parts. Part 1 will comprise an acute intervention study and part 2 will comprise a 4 week intervention study. Both studies will be double blind randomized cross-over designs. In the current study will use chocolate with a high flavanol content (CHF) and Chocolate with a high flavanol content (CLF).

Part 1: Acute study
In the first part of the study we will include 27 volunteers and evaluate the acute effects of 70g CHF or CLF consumption. Measures of vascular function and blood drawing will be performed at baseline and 2 hours after chocolate consumption This timeframe was chosen, because the effects on vascular function after chocolate consumption are most pronounced after two hours. The 27 volunteers that will participate in the acute study will also participate in the 4 week intervention study.

Part 2: Four week intervention
An additional 27 volunteers will be recruited to obtain a total of 44 participants for the second part of the study. In this part we will evaluate the effect of daily consumption of 70g CHF or CLF for 4 weeks. Measures of vascular function and blood drawing will be performed in the fasting state before and after each intervention period. Urine, feces and adipose tissue samples will be collected in the end of each intervention period. After each intervention period, volunteers will receive a HF/HE challenge. Postprandial measurements of vascular function and blood drawing will be performed before and 3 hours after consumption of the HF/HE shake. This timeframe was chosen, because previous studies have shown that the effects on vascular function after a HF/HE challenge are most pronounced after three hours.

Intervention

In the current study we will study the effect of 70g chocolate with a high flavanol content (CHF), which contains 2.2% flavanols of which 10.5% are epicatechins. As a control we will use 70g chocolate with a high flavanol content (CLF), which contains 0.2% flavanols of which 14% are epicatechins. Both CHF and CLF will only differ in flavanol content and will yield the same

amount of energy, theobromide, caffeine or potassium

The HF/HE shake will contain 95g of fat with high amounts of monounsaturated fatty acids (MUFA).

Study burden and risks

Subjects that will participate in both study parts will invest 22 hours. Participants that only participate in the second part, will invest 15 hours.

Chocolate consumption will result in an extra daily calorie intake.In order to prevent this weight gain, a personal dietary consult of approximately 15 minutes will be planned for each individual before start of the study. During this consult, the participants dietary habits will be discussed and based on this information, dietitians will advise the participant to refrain from certain food products in their normal daily habits, in order to compensate. These food products will comprise energy dense food snacks like biscuits, chips and desserts. These dietary guidelines will be similar for both intervention periods for all participants.

During the intervention period, participants need to visit the university weekly in order to collect their chocolate. During these visits, the weight of the participants will be measured. If a weight gain or loss (in case of over compensation) is recorded of >1kg compared to the starting situation, an extra consult will be planned in order to correct this. If participants increased >2kg in body weight at the end of the study, they will be referred to a professional dietician in order to assist them to regain their original body weight.

The consumption of the HF/HE shake is not expected to be associated with discomfort. All vascular measurements are non-invasive. Participant will donate at most 498ml of blood, dispersed over at least 15 weeks. Hb values of each participant will be measured before the start of the study to be sure that blood collection will not lead to anemia.

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

Caucasian Male
45-70y
BMI between 25 and 32 kg/m2

Exclusion criteria

Urine glucose concentrations outside normal ranges (>0,25 g/l)
Fasting blood glucose >7.0 mmol/L)
Systolic Bp >160 mmHg or diastolic Bp>100 mmHg
Blood Hb values < 8.4 mmol/L
Allergic to cow milk, dairy products or chocolate
Vegetarian
Tobacco smoker
Diagnosed with any long-term medical condition (e.g., diabetes, hemophilia, cardiovascular disease, anemia, gastrointestinal disease, renal failure)
No use of medication or food supplements known to interfere with: glucose homeostasis, blood pressure, Inflammation
If the participant don*t want to be informed about unexpected findings during the screening or study

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-01-2011
Enrollment:	44
Type:	Actual

Ethics review

Approved WMO Date:	22-11-2010
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL33506.081.10