# Comparison of Pure Epicatechin and Cocoa on Markers of Vascular Function

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The FLAVO-II study will be conducted as a three-armed, randomized, cross-over intervention trial aimed at comparing the effects of chocolate and pure epicatechin on vascular function.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Vascular hypertensive disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON41113

**Source**
ToetsingOnline

**Brief title**
Comparison of Epicatechin and Cocoa

### Condition

- Vascular hypertensive disorders

**Synonym**
endothelial function, Vascular function

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Wageningen Universiteit
**Source(s) of monetary or material Support:** Top Institute Food and Technology

### Intervention

**Keyword:** Cocoa, Epicatechin, Vascular function

## Outcome measures

### Primary outcome

The primary outcome is the acute response in Flow-Mediated Dilation (FMD) as a

marker of vascular function.

### Secondary outcome

The secondary outcomes are:

- plasma and urine epicatechin concentrations

- pulse wave analysis

- plasma nitric oxide and endothelin-1 concentrations

# Study description

### Background summary

Decreased vascular function is a risk factor for cardiovascular disease. Nutriton and lifestyle can significantly influence vascular function. The right choices of foods, rich in certain nutrients, can help lower the risk of myocardial infarction and stroke.

Foods with a high flavonoid content (such as tea, cocoa, apples and red wine) have already been shown to improve vascular function. This effect is thought to be due to the high-flavonoid content. Chocolate contains many types of flavonoids, one of which is epicatechin. Results from a previous study conducted at the Division of Human Nutrition suggest that epicaetchin can improve vascular function. It is possible, however, that other nutritients or components in chocolate improve the bioavailability of epicatechin resulting in more pronounced improvements in vascular function.

During the FLAVO-II study we aim to investigate whether epicatechin from chocolate is better absorbed than pure epicatechin (in capsule form) and if this in turn results in more pronounced improvements in vascular function. This will be done by asking participants to consume chocolate with varyining amounts of epicatechin in combination with capsules with varying amounts of epicatechin.

## Study objective

The FLAVO-II study will be conducted as a three-armed, randomized, cross-over intervention trial aimed at comparing the effects of chocolate and pure epicatechin on vascular function.

## Study design

During the FLAVO-II study, participants will attend three measurement days. Each measurement day will be separated by two weeks. This means that the final measurement day will take place exactly 4 weeks after the first measurement day. Each measurement day will last 8 hours and participants will be provided with a breakfast after 2 hours and a sandiwch at the end of the day.
During the two days prior to each measurement day, participants will be asked to avoid consumption of flavonoid-rich foods. They will be asked to consume no more than one cup of tea per day and to avoid consumption of cocoa, apples, red wine and product containing onion.
Every two weeks participants will visit the university in a fasted state for a measurement day. Fasted means that they will not be allowed to eat during the 8 hours prior to the first measurements. They will also be asked to refrain from exercising and avoid alcohol consumption during the 24-hours prior to a measurement day.
At each measurement day, height and weight will first be measured, ater which the first of five blood samples will be taken. Following the blood sample, baseline measurements of vascular function (FMD and PWA) will be done. Hereafter participants will be asked to consume 70g of chocolate plus two capsules. The chocolates and capsules will vary in epicatechin content. Participants will be required to consume each combination once. At this point subjects will also be provided with a low-flavonoid breakfast. Two hours after consuming the chocolate, vascular function measurements will be repeated. After consuming the chocolate, 7 blood samples of 20ml will be taken over a period of 8 hours by means of a venflon. During each measurement day, 24-hour urine samples will be collected.

## Intervention

Following baseline measurements, participants will be asked to consume 70g of cholclate and two capsules.
The chocolates capsules will vary in epicatechin content.
Combination 1: high flavonoid chocolate (97 mg epicatechin) + capsules without epicatechin
Combination 2: laag flavonoid chocolate + capsules with 100mg epicatechin
Combination 3: laag flavonoid chocolate + capsules without epicatechin (placebo intervention)

**Study burden and risks**

There are few risks related to participation in the study. Only healthy subjects will be allowed to participate in the study. To determine if subjects are healthy, they will be screened on several safety parameters including cholesterol, glucose and kidney function.

The dosage of epicatechin used during the study is equal to three times the 90th percentile of habitual intake in the Netherlands. This means that the dosage is equivalent to what could be consumed following a flavonoid-rich diet. A safety report for the epicatechin supplements has been provided to the METC.

Blood samples will be taken by means of a venflon which can be considered a significant burden for the participants. Blood samples will always be taken by trained medical staff following a standard operating procedure. In addition, three 24-hour urine samples will be collected which can be considered a burden for the subjects. All subjects will informed of these burdens prior to participation in the study.

# 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

- Age between 40 and 80 years
- BMI > 20 and <= 30
- Apparently healthy (no reported current or previous metabolic diseases, no history of cardiovascular diseases, no history of renal, liver or thyroid diseases, no history of gastrointestinal diseases, no diagnosed diabetes mellitus, fasting laboratory parameters within normal range as judged by the study physician: renal function (serum creatinine, ureum), liver function (ALAT, ASAT, *-GT), serum glucose and HDL, LDL and total cholesterol.

## Exclusion criteria

• Body mass index >30 or <=20 kg/m2
• Usage of CVD medication (e.g. anti-hypertensive and/or lipid-modifying medication, non-steroidal anti-inflammatory drugs, acetylsalicylic acid), antibiotics, corticosteroids or opioids and not able or willing to stop taking them from at least 4 weeks prior to the study
• Taking nutritional supplements and unwilling to discontinue
• Reported dietary habits: medically prescribed diet, slimming diet;
• Reported average alcohol consumption >= 3 glasses/d
• Reported intense sporting activities > 10 h/w
• Weight loss or weight gain of 5 kg or more during the last 2 months
• Smokers
• Vegetarians
• Problems with consuming the supplements or following the study guidelines
• Recent blood donation (i.e. 1 month) prior to the study and/or planned donation during and shortly after the study period
• Not agreeing to be informed about unexpected and medically relevant personal test-results, or not agreeing that their general practitioner will be informed about these results
• Participation in another biomedical trial less than 2 months before the start of the study or at the same time
• No signed informed consent form
• Unable to comply with the study procedure (e.g. holidays, urine collection, blood sampling)

# Study design

### Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Crossover |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Placebo |
| Primary purpose: | Prevention |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 18-08-2014 |
| Enrollment: | 20 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 22-05-2014 |
| 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 | NL48433.081.14 |