Relevance of Vascular Function Markers: Study on the Effects of Quercetin and Epicatechin on Blood Pressure and Vascular Function in (Pre)Hypertensive Subjects

Published: 30-08-2012
Last updated: 26-04-2024

The FLAVO-studie is a scientific study aimed at investgating if (and how) certain pure flavonoids can beneficially influence vascular function.

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

Summary

ID

NL-OMON39481

Source
ToetsingOnline

Brief title
The FLAVO-studie

Condition

- Vascular hypertensive disorders

Synonym
High blood pressure, vascular function

Research involving
Human

Sponsors and support

Primary sponsor: TI Food and Nutrition
Source(s) of monetary or material Support: Top Institute Food & Nutrition

Intervention

Keyword: Blood Pressure, Cocoa, Flavonoids, Vascular Function

Outcome measures

Primary outcome

The primary outcome is the change in Flow-Mediated Dilation (FMD) as a marker

of vascular function.

Secondary outcome

Secondary outcomes include:

- Blood Pressure

- Pulse-Wave Velocity

- Pulse Wave Analysis

- Vasomotion

- Biomarkers of vascular and endothelial function

- Biomarkers of inflammation

- Glucose resistance (HOMA-IR)

Study description

Background summary

Decreased vascular function and increased blood pressure are both risk factors for cardiovascular disease. Nutrition and lifestyle can significantly influence both vascular function and blood pressure. The right choice of foods, rich in

certain nutrients, can help lower the risk of myocardial infarction or stroke.

Foods with a high flavonoid content (such as tea, cocoa, red wine, apples and onions) have already been shown to have a blood pressure-lowering effect. These effects are often thought to be due to the high flavonoid content, however, because these foods contain many different types of flavonoids, it is difficult to say which flavonoid in particular may have a beneficial role.

During the FLAVO-studie, we aim to investigate if (and how) certain pure flavonoids can beneficially effect vascular function. This will be done by providing participants with capsules containing two different types of flavonoids. Participants will be asked to consume these flavonoid capsules for 4 weeks. Measurements will be taken be and after the 4-week intervention period.

Study objective

The FLAVO-studie is a scientific study aimed at investgating if (and how) certain pure flavonoids can beneficially influence vascular function.

Study design

The study will commmence with a run-in week. During the run-in week, participants will receive dietary advice asking them to refrain from consuming food products known to have a high flavonoid content (such as tea, cocoa, apples, red wine and onions).

Following the run-in week, participants will be asked to follow three intervention periods of 4 weeks. Each intervention period will be separated by a washout period. During the washout period, participants will not have to consume any capsules and will only be asked to follow the dietary advice.

During an intervention period, participants will be asked to consume capsules containing either a flavonoid supplement or a placebo capsule (two capsules per day). Participants will be asked to consume one capsule at lunch and one at dinner - with a glass of water.

Every four weeks, participants will be asked to visit the university following an overnight fast. During these visits, various measurements of vascular function will be taken. On the last day of each intervention period, a number of measurements (including a blood sample) will be taken twice - once in the morning and again two hours after consumption of a final supplement. Every two weeks additional blood samples will be taken.

Intervention

During an intervention period, participants will be asked to consume capsules containing either flavonoid supplements or placebo capsules (two capsules per day). Participants will be asked to consume one capsules during lunch and one during dinner - with a glass of water.

The flavonoid supplements which will be used are epicatechin (100mg/day) and quercetin-3-glucoside (160mg/day). The dosage of the supplements corresponds to 3 times the 90th percentile of habitual intake in the Netherlands.

Study burden and risks

Risks for the subjects are considered low. Only healthy subjects with a systolic blood pressure between 125 and 159mmHg will be included in the study. To determine if subjects are healthy, they will be screened on several safety parameters including liver and renal function.

The dosage of flavonoids provided (160mg for quercetine-3-glucoside and 100mg for epicatechin) are equal to three times the 90th percentile of habitual intake in the Netherlands. This means that the dosage provided is equivalent to what could be consumed following a flavonoid-rich diet. A safety report of both supplements to be used has been provided to the METC.

There is a chance of bruising as a result of venepuncture and some subjects may feel light-headed or experience a slight headache as a result of nitroglycerine administration. In such cases, subjects will be advised to remain seated until the effects have subsided and to avoid physical activity immediately following administration.

Parameters of liver and renal function as well as whole blood cell count will be taken and analysed every two weeks in order to monitor the health status of the subjects during the study period.

In contrast, it is hypothesized that the consumption of flavonoid supplements will decrease blood and improve vascular function.

Contacts

Public
TI Food and Nutrition

Nieuwe Kanaal 9A
Wageningen 6709PA
NL
Scientific

TI Food and Nutrition

Nieuwe Kanaal 9A
Wageningen 6709PA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Systolic Blood Pressure between 125 and 159 mmHg
• Age between 30 and 80 years
• BMI > 20 and <= 40

Exclusion criteria

• Hisory of CVD
• Diabetes
• Usage of cholesterol-lowering medication
• Usage of non-steroidal anti-inflammatory drugs (acetylsalicylic acid, ibuprofen, naproxen) and not able or willing to stop taking them from at least 4 weeks prior to the study
• Smokers
• Weight loss or weight gain of 5 kg or more during the last 2 months

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-10-2012
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	30-08-2012
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	15-02-2013
Application type:	Amendment
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	NL40772.081.12