Chocolate Intervention to Reduce Chronically Elevated blood pressure trial* CIRCE trial

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To assess the effect of cocoa-containing drinks either rich in flavanols or rich in flavanols and theobromine on blood pressure in untreated subjects with high normal blood pressure (prehypertension) or grade I hypertension as measured by 24-hours...

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

Summary

ID

NL-OMON32431

Source
ToetsingOnline

Brief title
CIRCE trial

Condition

- Vascular hypertensive disorders

Synonym
high blood pressure, hypertension

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 (UFHRI)

Intervention

Keyword: cocoa, hypertension, prehypertension, randomised clinical trial

Outcome measures

Primary outcome

Difference in 24-hour ambulatory blood pressure for both cocoa treatments

compared to the placebo treatment.

Secondary outcome

The difference between the placebo treatment arm and the cocoa treatment arms

in:

Augmentation index, central (aortic) blood pressure and pulse wave velocity as

assessed by the Sphygmocor device.

Systemic vascular resistance as assessed by Finapres.

Endothelial function as assessed by Endopat2000

Insulin sensitivity, lipid profile measured with standard laboratory

techniques.

Platelet aggregation and function.

Mood and psychological well-being (via self-report questionnaires)

Study description

Background summary

Persons with high-normal blood pressure or prehypertension and grade I hypertension have an increased risk for cardiovascular disease. According to current recommendations of the European Society of Hypertension (ESH) persons with high-normal blood pressure and grade I hypertension with a maximum of 2 additional risk factors and no evidence or history of cardiovascular disease are aimed at improving life style. However, implementation of these life style

changes (e.g. salt reduction, weight loss) is notoriously difficult. Recent studies have shown that consumption of dark chocolate may significantly reduce blood pressure. Therefore dark chocolate might be a possible non-pharmacological intervention to lower blood pressure in addition to life style advice. Current trials were only aimed at stage I and II hypertensive individuals and did not include a real placebo. Moreover, the substance or substances, responsible for the blood pressure lowering effect of cocoa have not been fully established. Both flavanols and theobromine have been considered as substances which may be responsible for the blood pressure lowering effect. Apart from their blood pressure lowering effect flavanols and theobromine have been implicated in beneficially altering lipid profile, platelet aggregation and feeling of well-being.

Study objective

To assess the effect of cocoa-containing drinks either rich in flavanols or rich in flavanols and theobromine on blood pressure in untreated subjects with high normal blood pressure (prehypertension) or grade I hypertension as measured by 24-hours ambulatory blood pressure.

Study design

Randomized double-blind placebo-controlled cross-over trial.

Intervention

Three weeks daily consumption of a cocoa drink rich in flavanols and rich in theobromine, a cocoa drink rich in flavanols but low in theobromine and a placebo drink in random order.

Study burden and risks

In total, the study will take 17 weeks to complete. During this period study participants will be asked to visit the hospital 10 times, with the first visit lasting approximately 30 minutes, the second 15 minutes visit 3 2 hours visits 5,7,9 approximately 4 hours and visit 4,6,8,10 approximately 10 minutes. At baseline (after randomisation) and after all three treatment periods fasting blood samples will be taken, non-invasive central (aortic) blood pressure measurements, non-invasive endothelial function measurements and 24-hour blood pressure measurements will be done. The risks associated with this study consist of the possible side-effects related to the chocolate containing drinks. These risks are considered low because of the widespread safe use of chocolate containing products and the close monitoring of study participants with predefined stop criteria. Clinical trials investigating chocolate containing foods or food supplements have safely used flavanols and theobromine in doses exceeding the dose used in this study. The benefits of participating

in this study are the possible blood pressure lowering effects of chocolate containing drinks.

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

informed consent
age 40-70 years
men and postmenopausal women
blood pressure 130-159/85-99 mmHg
maximum of 2 risk factors according to ESH 2007 guidelines
BMI > 18 and < 30 g/m2
not on active anti-hypertensive treatment with at least six weeks since last use of antihypertensive medication

haematological and clinical chemical parameters within the normal reference range
willing to restrict daily intake of coffee below 4 cups and to refrain from dark chocolate and to refrain from supplements that contain polyphenols from the screening visit to the end of the study

Exclusion criteria

previous cardiovascular event(s) (stroke, TIA, angina, myocardial infarction, heart failure)
total cholesterol > 8.0 mmol/L
diabetes mellitus, defined as fasting glucose > 7.0 mmol/L or use of glucose lowering drugs
reported alcohol consumption > 28 alcohol units/week
other diseases or oral medication affecting blood pressure
being an employee of the AMC
currently on a medically prescribed diet, or slimming diet
reported intense sporting activities > 10 h/w
being lactose intolerant

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	42
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	NL24636.018.08