Chocolate blood pressure lowering trial

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24612

Source
Nationaal Trial Register

Brief title
CIRCE

Health condition

Hypertension
Prehypertension
Lifestyle intervention

Sponsors and support

Primary sponsor: Academic Medical Center
University of Amsterdam
The Netherlands
Source(s) of monetary or material Support: Academic Medical Center
Unilever

Intervention

Outcome measures

Primary outcome

The difference in blood pressure between the placebo treatment arm and the cocoa treatment arms as assessed by 24-hour ambulatory blood pressure measurement.

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.

* 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

Background:

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. Dark chocolate might be a possible non-pharmacological intervention to lower blood pressure in addition to life style advice.

Objective:
To assess the effect of cocoa-containing drinks 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.

Study population:
42 healthy human volunteers, men and postmenopausal women, 40 - 70 yrs old, with high-normal blood pressure or grade I hypertension (blood pressure between 130-159 and/ or 85-99 mmHg) with a maximum of 2 risk factors according to the 2007 ESH guidelines and

who have not received anti-hypertensive treatment the last 6 weeks.

Intervention:
Three weeks daily consumption of a cocoa drinks

Main study parameters/endpoints:
Difference in 24-hour ambulatory blood pressure for both cocoa treatments compared to the placebo treatment.

Study objective

Dark chocolate containing drinks lower blood pressure in prehypertensive and grade I hypertensive subjects with 2 or less additional cardiovascular risk factors and theobromine is an essential component of cocoa for obtaining a blood pressure lowering effect

Study design

Aim: inclusion finalized by april 2008

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. In between 2 weeks washout periods.

Contacts

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Eligibility criteria

Inclusion criteria

1. Written informed consent

2. Age 40-70 years

3. Men and postmenopausal women

4. Blood pressure 130-159/85-99 mmHg

5. Maximum of 2 risk factors according to ESH 2007 guidelines

6. BMI > 18 and < 30 g/m2

7. Not on active anti-hypertensive treatment with at least six weeks since last use of antihypertensive medication

8.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
determined by examination at information meetings

Exclusion criteria

1. Previous cardiovascular event(s) (stroke, TIA, angina, myocardial infarction, heart failure)

2. Total cholesterol > 8.0 mmol/L

3. Diabetes mellitus, defined as fasting glucose > 7.0 mmol/L or use of glucose lowering drugs

4. Reported alcohol consumption > 28 alcohol units/week

5. Other diseases or oral medication affecting blood pressure

6. Currently on a medically prescribed diet, or slimming diet

7. Reported intense sporting activities > 10 h/w

8. Being lactose intolerant

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2008
Enrollment:	42
Type:	Actual

Ethics review

Positive opinion

Date:	23-09-2008
Application type:	First submission

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
NTR-new	NL1393
NTR-old	NTR1453
Other	AMC METC : 08/237
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A