Chocolate blood pressure lowering trial

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24612

Bron
Nationaal Trial Register

Verkorte titel
CIRCE

Aandoening

Hypertension
Prehypertension
Lifestyle intervention

Ondersteuning

Primaire sponsor: Academic Medical Center
University of Amsterdam
The Netherlands
Overige ondersteuning: Academic Medical Center
Unilever

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Aim: inclusion finalized by april 2008

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-11-2008
Aantal proefpersonen:	42
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	23-09-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1393
NTR-old	NTR1453
Ander register	AMC METC : 08/237
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A