The effect of sodium chloride intake on blood pressure response to coffee

Published: 03-04-2012
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to explore the effect of sodium intake on the coffee-induced increase in blood pressure

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

Summary

ID

NL-OMON37848

Source
ToetsingOnline

Brief title
Coffee and salt intake

Condition

- Vascular hypertensive disorders

Synonym
Hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: blood pressure, Caffeine, Sodiumchloride

Outcome measures

Primary outcome

response to coffee intake of blood pressure Dinamap and Nexfin) and cardiac

output (Pulse contour method applied to continuous blood pressure signal that

is measured at the finger using Nexfin)

Secondary outcome

sodium and creatinine excretion in urine; plasma caffeine concentration before

and 2 hours after intake of 2 cups of coffee

Study description

Background summary

Caffeine intake increases blood pressure acutely, an effect that deminishes over time when coffee is used regularly. This effect is likely to be caused by antagonism of the vasodilator action of endogenous adenosine. Recently, high sosium intake has been shown to augment the vasodilator action of adenosine in animals. We hypothesize that high sodium intake also augments the blod pressure response to caffeine. If true, the current epidemiological data base on the cardiovascular safety of caffeine consumption needs to readressed taking into account the modifying role of sodium intake.

Study objective

to explore the effect of sodium intake on the coffee-induced increase in blood pressure

Study design

Non-blinded randomized cross-over design.

Intervention

All volunteers will use a high (6 gram/24 hours) and low (12 gram/24 hours) sodium chloride diet (in random order; 5 days on each diet, both periods separated by at least 4 days). At the end of each period, 24 hour urine is

collected to assess sodium excretion. Volunteers will abstain from caffeine containing beverages, alcohol and nicotine for at least 24 hours. The blood pressure response to two cups of caffeine containting coffee, prepared according to standardized procedures, will be measured. Venous blood is sampled before and two hours after coffee administration to measure caffeine concentration.

Study burden and risks

No relevant risk is anticipated

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

Signed informed consent.
At least 18 years of age.

Exclusion criteria

Use of any medication or recreational drugs (exept oral anticonception in female participants)
Hypertension (defined as SBP > 140 mmHg and/or DBP > 90 mmHg as measured after at least 5 minutes in supine position by standard auscultatory measurements)
Difference in blood pressure between the two arms of 10 mmHg or more (systolic)
Alcohol consumption > 2 units/day
Any cardiovascular abnormality as detected during routine history and physical examination.
BMI > 25

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-04-2012
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	03-04-2012
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-04-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL39999.091.12

Study results

Date completed:	01-07-2012
Actual enrolment:	15