Study on the effects of sodium and potassium on blood pressure, vascular function and renal function in untreated (pre)hypertensive subjects

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The primary objective is to determine the effect of (1) increased sodium intake and (2) increased potassium intake on flow-mediated dilation (FMD) and systolic blood pressure (SBP) in untreated (pre)hypertensive subjects

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35685

Source
ToetsingOnline

Brief title
KaNa-trial

Condition

- Other condition
- Vascular hypertensive disorders

Synonym
elevated blood pressure, vascular funtion

Health condition

nierfunctie (estimated glomerular filtration rate)

Research involving
Human

Sponsors and support

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

Intervention

Keyword: blood pressure, potassium, sodium, vascular function

Outcome measures

Primary outcome

The primary parameters is flow-mediated dilation (FMD).

Secondary outcome

Secondary parameters involve: diastolic blood pressure (DBP), centrale blood pressure, 24-hour ambulatory blood pressure, augmentation index (Aix), pulse wave velocity (PWV), vasomotion, estimated glomerular filtration rate (eGFR) and plasma biomarkers of endothelial function and low-grade inflammation, as asymmetric dimethylarginine (ADMA), endothelin-1, nitric oxides (NOx), monocyte chemoattractant protein (MCP-1), soluble endothelin selection (sE-selectin), soluble-thrombomodulin (sTM), von Willebrand factor (vWF), the cell adhesion molecules sVCAM-1 and sICAM-1, C-reactive protein (CRP), serum amyloid A (SAA), interleukin 6 (IL-6), interleukin 8 (IL-8) and tumor necrosis factor-α (TNF-α)

Study description

Background summary

Identifying factors that influence vascular function and blood pressure has important implications for preventing CVD, which is the leading cause of death

in modern societies. A large body of evidence supports the view of associations between sodium and potassium intake and blood pressure, but the effects of these minerals on vascular function and renal function are less conclusive.

Study objective

The primary objective is to determine the effect of (1) increased sodium intake and (2) increased potassium intake on flow-mediated dilation (FMD) and systolic blood pressure (SBP) in untreated (pre)hypertensive subjects

Study design

Randomized, double-blind, placebo controlled cross-over feeding study .

Intervention

One-week run-in period, followed by 3 periods of 4 weeks intervention. During the run-in period and intervention periods the subjects will remain on a low-sodium, low-potassium diet, which provides 2 grams of sodium (5 grams NaCl) and 2 grams of potassium on a daily basis. After the run-in, the subjects will receive in random order for periods of 4 weeks:
1. Sodium chloride supplements (increased sodium intake of 3 g/d = 7.5 g/d NaCl),
2. Potassium chloride supplements (increased potassium intake of 3 g/d) or
3. Placebo (cellulose) supplements (*low sodium, low potassium phase*).

Study burden and risks

The reached sodium and potassium intake during the different interventions falls within the range that Dutch persons consume. Next to that, only persons that are apparently healthy (besides their elevated blood pressure) can participate. Important is that they have a good renal function and therefore the renal function will be determined during screening. It is likely that the blood pressure will increase during the period with increased sodium intake and decrease in the period with increased potassium intake. These changes will be temporary. If SBP becomes 160 mm Hg or above, the subject and the general practitioner will be informed. There is no direct (health-related) benefit for the participant. A burden for the subjects may be the restricted diet, the consumption of the diet at the Division of Human Nutrition, the consumption of capsules and the measurements during the test days.

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

Systolic Blood Pressure between 130-159
No use of cardiovascular medication
Age 40 years and over

Exclusion criteria

Chronic diseases (as diabetes, cardiovascular diseases, renal impairment)

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):	12-03-2012
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	21-12-2011
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	18-06-2012
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	NL38415.081.11

Study results

Date completed:	09-08-2012
Actual enrolment:	40