Effect of dietary proteins on blood pressure

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

Summary

ID

NL-OMON33979

Source
ToetsingOnline

Brief title
ProPres

Condition

- Vascular hypertensive disorders

Synonym
elevated bloodpressure

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Campina,DSM Food Specialties,Friesland Nutrition,TIFN (ministerie EZ;bedrijven;universiteiten),Unilever,VION, CSM allen via TIFN

Intervention

Keyword: bloodpressure, dietary protein, endothelial function, sympathetic activity

Outcome measures

Primary outcome

bloodpressure (fastened and ambulantory)

Secondary outcome

Heartrate volume and cardiac output, forearm bloodflow, renal bloodflow,

sympathetic activity, activity of the renin-angiotensin-aldosteron system,

glomerular filtration rate, sodium homeostase, acid production, endothelial

function.

Study description

Background summary

Lowering blooedpressure in humans with high-normal or untreated type 1 hypertension can contribute significantly to a reduction of morbidity and mortality due to cardiovascular diseases, because of the high incidence within the population. Food could play an important role in this. From previous studies it has been shown that food rich in protein, can reduce bloodpressure. It is however still unknown if the proteins itself are responsible for this reducion and also the underlying mechanism is still not yet clear.

Study objective

The primary objective of the study is to demonstrate a difference in changes in fasting blood pressure and 24-hour ambulatory blood pressure after 4 weeks on a diet with a high protein content or a diet with a high carbohydrate content. Secondary objectives are to explore potential mechanisms of the blood pressure effect of dietary proteins by studying the postprandial responses of potentially relevant variables to high protein and high carbohydrate meals, on the first day of the intervention as well as after 4 weeks. The secondary objectives will be studied in a subgroup of the total study population.

Study design

The study has a double-blind randomised two-arm parallel design.
After screening, subjects will enter a 2 week run-in phase, where they will consume a standard diet (30% fat, 55% CHO, 15% protein). At the end of this run-in period, subjects will be randomised to one of the dietary groups for 4 weeks: a high-protein group (30% fat, 45% CHO, 25% protein) and a high carbohydrate group (30% fat, 55% CHO, 15% protein). Primary outcome variables (fasting blood pressure and 24-hour ambulatory blood pressure) will be measured at the end of the run-in phase, at the start of the randomised phase and at the end of the randomised phase. In the subgroup the secondary outcome measures will be assessed at the beginning and end of the randomised phase.

Intervention

The intervention will consist of a fixed diet for 6 weeks, whereas there will be supplements provided after 2 weeks.
During supplementation, the high-protein group will have a 60 gr reduction of carbohydrates in their diet, that will be replaced by 60 gr protein supplement. This protein supplement consists of milk, egg (60%) and soy and pea proteins (40%) (3 x 20gr supplement).
The diet of the high-carbohydrate group will also be reduced with 60 gr of carbohydrate and this will be replaced by maltodextrin equal to 60 gr of carbohydrate (3 x 20gr supplement).
Bloodpressure will be taken every week. In a subgroup there will be measurements determining mechanisms involved in the regulation of bloodpressure. These will be forearm bloodflow, kidney blood flow & filtration rate, heart rate volume, cardiac output and arterial stifness. Subsequently there will be several bloodsamples taken. These measurements will take place after two and six weeks.

Study burden and risks

Subjects will be asked to strictly adhere to a diet, partly through supplements, for 6 weeks and to adhere to physical activity recommendations on 2-3 days during this period. The measurements are easily sustainable and are very low risk. Bruising from blood sampling may occur. The duration of the study is 6 weeks and requires 9 visits to the lab, ranging between 30 and 60 minutes, including screening. In the subjects participating in the full protocol with measurement of secondary parameters, an extra two whole days at the lab are required.

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

(mild) hypertension

Exclusion criteria

renal function disturbances
food allergy
recent weightloss > 3 kg
plasma bloodglucose > 7,0 mM

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2008
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	06-08-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	30-09-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL23226.068.08
Other	TC=1362