Acute effects of dietary proteins, that differ in amino acid composition, on blood pressure-related mechanisms

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

Summary

ID

NL-OMON36655

Source
ToetsingOnline

Brief title
AAPRES: dietary proteins and blood pressure-related mechanisms

Condition

- Vascular hypertensive disorders

Synonym
Elevated blood pressure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Blood pressure, Hypertension, Mechanisms, Proteins

Outcome measures

Primary outcome

The primary outcome parameter is the difference in postprandial vasodilation between the different proteins and the association with differences in the responses of vasodilating factors.

Secondary outcome

As secondary endpoints, differences in postprandial renal sodium excretion and vascular function changes between protein supplements will be investigated. In addition, differences between protein and carbohydrate intake and between the two carbohydrate sources will be evaluated.

Study description

Background summary

There is growing evidence for a beneficial effect of dietary protein on BP. We previously showed that intake of a mixture of four proteins reduced BP compared to maltodextrin intake, and induced postprandial vasodilation and changes in markers of endothelial function. It is hypothesized that the individual protein sources of the mixture might differentially influence postprandial vasodilation, the factors that might be responsible for these differences, and vascular function parameters due to differences in amino acid composition. In addition, we found that postprandial and 24-hour urinary sodium excretion were lower after protein intake compared to maltodextrin intake. This in contradiction with findings in published literature.

Study objective

The primary objective is to investigate if there are differences in the acute postprandial vasodilating effect between different protein sources and if these differences are associated with differences in the responses of vasodilating

factors. Secondary objectives are to investigate (1) if there are differences in postprandial vascular function changes and renal sodium excretion between different protein sources, (2) if there are differences in the acute postprandial vasodilating effect, response of vasodilating factors, renal sodium excretion and vascular function changes between these proteins and maltodextrin, and (3) if there are differences in the acute postprandial vasodilating effect, response of vasodilating factors, renal sodium excretion and vascular function changes between maltodextrin and sucrose, another source of carbohydrate.

Study design

The study has a double-blind randomized 6-arm cross-over design. The total study period comprises 8 weeks consisting of a 2-week run-in period, followed by a 6-week treatment period. Subjects will be randomized to one of 6 treatment orders at the end of the run-in period if they meet the inclusion criteria with respect to BP. Treatments consist of a single dosage of a protein or carbohydrate and will be separated by a wash-out of at least 1 week.

Intervention

During the 8 week study period, dietary intake of the subjects will be standardized with respect to macronutrient composition (15% protein, 30% fat (<10% saturated fat), 55% carbohydrates (recommended diet according to the Dutch Health Council, 2006)). All foods will be provided to the subjects the day before each of the 6 clinical investigation days (CID*s). During the CID*s subjects receive a supplement in liquid form containing 0.6 gram protein per kilogram body weight or an isocaloric amount of carbohydrate for breakfast. Measurements of hemodynamics and vascular function will be performed and venous blood samples will be collected at regular time intervals before breakfast and over a 4-hour postprandial period.

Study burden and risks

The total study period comprises 8 weeks with a total of 8 visits and 6 CID*s. A total of 80 ml blood will be taken on each CID. Urine will be collected over the 4-hour postprandial period. No harm from the dietary intervention is to be expected. All supplements used during this study are cleared for human use and are prepared according to GMP regulations. The administration of the amount of 0.6 gram protein per kilogram body weight for breakfast will not have any health risks and is performed previously without any side effects in the study of Claessens et al. The amount of 0.6 gram per kilogram body weight for breakfast is within the range of the RDA of proteins according to the WHO. All measurements will be executed by trained personnel. The use of cuffs during different measurements can feel uncomfortable but is only for a short period of time and not harmful. Placement of catheters may be associated with some

bruising.

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

- healthy overweight men and women (BMI 25-35 kg/m2)
- high normal blood pressure or untreated grade I hypertension (SBP 130-159 mm Hg and/or DBP 85-99 mm Hg)
- age >=20 and <=70 y
- no smoking
- weight stable in last 3 months (± 2 kg)

Exclusion criteria

- presence of urinary protein (stick test)
- eGFR < 60 ml/min/1.73 m2
- fasting glucose > 7 mmol/L
- use of prescription medication that could influence BP or vascular function

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-02-2011
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	20-12-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-02-2011
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

ID: 20220
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL34527.068.10
OMON	NL-OMON20220