Effect of arginine-rich dietary protein on postprandial metabolism, inflammation and endothelial function

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON34166

Source
ToetsingOnline

Brief title
Pea Protein and Postprandial Response (PEAstudy)

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, metabolic syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: overheid (provincie)

Intervention

Keyword: arginine, dietary protein, metabolic syndrome, postprandial response

Outcome measures

Primary outcome

main study parameters include postprandial responses in metabolic factors

(insulin, glucose, triglycerides), inflammation markers and endothelial

function (tonography) .

Secondary outcome

secundary studie parameters are changes in satiety markers (GLP) and changes in

oxidative stress as measured in PBMCs

Study description

Background summary

Arginine is potential interesting considering the metabolic syndrome. Studies so far indicated both long-term effects, as well as acute - postprandial - actions; especially when metabolism is already challenged, e.g. in diabetic patients or after a high-fat meal. However, whether arginine-rich proteins are equally effective is not known. Moreover, a careful examination of the effect of (arginine rich) protein on postprandial (dys)metabolism and inflammation is hardly performed.

Study objective

The primary objective of the present study is to investigate the postprandial effect of arginine-rich protein (i.e. pea-protein) on metabolic control, inflammation and endothelial function after a high-fat meal in subjects with the metabolic syndrome. Secondly, the effect of an arginie-rich protein will be compared to protein low in arginine (i.e. gluten protein). Finally, it will be evaluated whether the protein-hydrolysate has additional advantages.

Study design

Double-blind, controlled challenge study, cross-over Latin square design

Intervention

High-fat meal without (CON) or with added protein: pea-protein (PP), gluten-protein (GP) or their hydrolysates (PPH and GPH respectively)

Study burden and risks

During a screening visit 6 ml blood will be drawn after an overnight fast and body weight, length, waist and blood pressure will be measured. An oral glucose tolerance test will be performed. A general and medical questionnaire will be used.
During the study period of 8 weeks each participant will visit the University on 5 days, separated by at least one week, and will consume within 15 minutes a milkshake containing 95 grams of fat with or without added 30 g protein. Blood will be collected both before consuming the milkshakes (baseline, T=0) and every hour after consumption of the shakes until 6 hours (T=1-6), using a venous cathteter (venflon0. In total 100 mL will be sampled during a single test day. Endothelial function (ED) will be measured at T=0, T=3 and T=6 hrs. Body composition of the participants will be measured in the Bod Pod.

The time investment requested from the participants is 1 hour at the information meeting, 2.5 hours at a screening session, 5 x 7 hours at the intervention days. The risks associated with venous blood drawing using the venflon technique, ED and body composition measurements are minimal. Blood sampling can result in a local haematoma, and can cause discomfort. The consumption of the milkshakes is not expected to be associated with discomfort, but could, in rare cases, have adverse effects such as a mild gastrointestinal discomfort (belching, flatulence or loose stools).

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

male
* central obesity: waist circumference >=94 cm
plus any one of the following four factors:
* raised triglyceride level: >=1.7 mmol/L;
* reduced high-density lipoprotein (HDL) cholesterol: <1.03 mmol/L
* raised blood pressure: systolic blood pressure >=130 mmHg or diastolic BP >=85 mmHg or use of blood pressure lowering medication
* raised fasting plasma glucose >= 5.6 mmol/L

Additional inclusion criteria:
* age 45-65 years
* body weight should be stable for at least 6 months
* stable exercise habits during the last 6 months, and not participating in any vigorous exercise program

Exclusion criteria

* (undiagnosed) diabetes - but not impaired fasting glucose (IFG) and/or impaired glucose tolerance (IGT) as evaluated by an oral glucose tolerance test at screening (plasma glucose: fasting > 7.0 and/or 2-hours > 11.1 mmol/L)
* High triglyceride levels (> 5 mmol/L) or high blood pressure (> 160/95 mmHg) at screening
* Low haemoglobin level at screening (< 7.5 mmol/L)
* active hearth disease, i.e. history of myocardial infarction or angina pectoris
* following, or have recently followed a (weight-loss) diet
* drug uses knowing to interfere with the objectives of the study
- oral corticosteroids, lipid-lowering drugs (statins)
- ACE-inhibitors

* Allergic to cow milk / dairy products or gluten
* vegetarians
* Received inoculations within 2 months of starting or planned to during the study
* Donated or intended to donate blood 2 months before till two months after the study
* abuse of drugs and/or alcohol
* tobacco smoker
* participation in another biomedical study within 1 month before the first screening visit
* Not wanting to be informed about chance-findings during screening

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	04-06-2010
Application type:	First submission
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	NL32078.081.10