Effect of different protein diets on glucose and insulin metabolism and substrate partitioning

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The presently proposed study aims to investigate how dairy proteins compare to vegetable protein and carbohydrate sources leads to glucose and insulin metabolism and substrate partitioning.

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

Summary

ID

NL-OMON33527

Source
ToetsingOnline

Brief title
Protein diets and glycemic and insulinemic control

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, obesity

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: zuivelstichting van de Nederlandse Zuivel Organisatie

Intervention

Keyword: 24 hr glycemic and insulinemic control, protein diets, substrate partitioning

Outcome measures

Primary outcome

24 hr glycemic control

insulin

Secondary outcome

substrate partitioning, hunger and satiety questionnaires, FFA, CRP, leptin,

TG, CCK, GLP-1, adiponectin, ghrelin, glucagon, IL-6, TNFalpha, MCP-1, IL-1,

IL-8, s-ICAM and s-VCAM

Study description

Background summary

A high protein diet in type 2 diabetics for 5 weeks showed an improvement of the 24 h glycemic profile and lower Triglyceride (TG) and Free Fatty Acids (FFA) [9]. It suggests that the low GI property of (dairy) protein gives glycemic improvements leading to a better body weight control despite the strong insulinotropic properties, which are comparable to high GI food. This hints to an improvement of the insulin sensitivity due to the stimulatory insulin secretion effect using high (diary) protein diets. Therefore, it is important to get a better insight in the role of dietary (dairy) proteins on glycemic profile and in particular its role on insulin metabolism and substrate partitioning. Also the role of diary proteins compare to other protein sources in relation to the post-prandial response on metabolic markers is not known. For that reason, experimental studies with different (dairy) protein and GI diets will be investigated in this study.

Study objective

The presently proposed study aims to investigate how dairy proteins compare to vegetable protein and carbohydrate sources leads to glucose and insulin metabolism and substrate partitioning.

Study design

Subjects are exposed to four different diets. To have a same baseline condition before each diet, subjects have to standardize the 3 days before the tests. Therefore food-intake and activity diaries have to be filled out before the first test day and repeated before the other test days.
Each respiration chamber visit starts after the continuous glucose monitoring system (CGMS) placement plus preparation time at 21.00h and ends 36 hours later at 9.00h. The first twelve hours are to accustom to the respiration chamber. Then, energy expenditure measurements are made during 24 hours at a temperature of 22°C. During the respiration chamber visit, hourly (during daytime) sleepiness-questionnaires and daily sleep-questionnaires will be filled out. Also VAS satiety scale questionnaire has to be filled out before and hourly after a meal. Also bloodsamples will be taken at 0, 30, 60, 120 and 240 minutes postprandially after the three meals.

Intervention

1. 15% dairy protein and low GI
2. 25% dairy protein and low GI
3. 15% vegetable protein and low GI
4. 15% dairy protein and high GI (specific details of the diet in appendix)

Study burden and risks

Venapunctures can occasionally cause a local haematoma or bruise to occur.

Contacts

Public
Universiteit Maastricht

Abraham Kuyperstraat 14
6136 DE Sittard
Nederland
Scientific
Universiteit Maastricht

Abraham Kuyperstraat 14
6136 DE Sittard
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy men
BMI between 18.5 - 25 kg/m2
Jounger than 35 years old

Exclusion criteria

Diabetes Mellitus
Hypertension
Hypotension
Cardiovasculaire diseases
Asthma and other obstructive pulmonary diseases
Lactose intolerant

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-03-2009
Enrollment:	14
Type:	Actual

Ethics review

Approved WMO

Date:	02-02-2009
Application type:	First submission
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	NL24804.068.08