The effects of protein supplementation on glucose homeostasis in type 2 diabetes

Published: 05-12-2006
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Investigate the optimal dose of such an insulinotropic mixture.

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

Summary

ID

NL-OMON30023

Source
ToetsingOnline

Brief title
Protein supplementation and glucose homeostasis

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
non-insulin dependent diabetes, Type 2 diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,DSM Food Specialties

Intervention

Keyword: Glucose homeostasis, Insulin, Protein, Type 2 diabetes

Outcome measures

Primary outcome

Glucose and insulin homeostase.

Secondary outcome

Plasma amino acid profiles

Study description

Background summary

The inulinotropic effects of protein hydrolysate/amino acid ingestion have been shown to regulate blood glucose homeostasis in both type 2 diabetes patients and normoglycemic controls

Study objective

Investigate the optimal dose of such an insulinotropic mixture.

Study design

4h dose-response study in which three different mixtures will be compared to a placebo.

Intervention

Consumption of a protein/aminio acid mixture

Study burden and risks

4, 4 hour tests in which blood (8mL) will be sampled every 30 min via a venous catheter

Risks as the result of participation in this experiment are minimal. At the

site of the catheter a hematoma could occur. The ingested protein beverages contain proteins which are part of the normal diet and are therefore harmless.

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

Longstanding (>5 yrs) type 2 diabetes
Age between 40 and 70 yrs
Oral blood glucose lowering medication

Exclusion criteria

Exogenous insulin use
Microalbinuria

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2007
Enrollment:	30
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	05-12-2006
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	NL13600.068.06