Effects of 10 gram of a protein hydrolysate on serum insulin and glucose levels in patients with type 2 diabetes mellitus and the influence of varying carbohydrate loads

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28945

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Type 2 diabetes mellitus

Sponsors and support

Primary sponsor: DSM Food Specialties
Source(s) of monetary or material Support: DSM Food Specialties

Intervention

Outcome measures

Primary outcome

Serum concentrations and AUC of glucose and insulin

Secondary outcome

N/A

Study description

Background summary

There is accumulating evidence that amino acids such as leucine play a role as insulin secretagogues. One possible clinical application that is currently explored is a protein hydrolysate. Research with this product has shown that co-ingestion of this product with carbohydrate augments the insulin response and enhances glucose disposal.

Previous experiments were also carried out with a high dose of carbohydrate. It is not known if the hydrolysate is efficacious in the presence of lower carbohydrate doses.
The current study will therefore address the efficacy of a fixed dose of the hydrolysate, combined with either a low or a high carbohydrate load in lowering blood levels of insulin and glucose in patients with T2DM.

Objectives:

The objective is to assess the effect of a 10-g dose of the hydrolysate on blood levels of insulin and glucose in patients with T2DM, combined with a 25 or 50g carbohydrate load.

Study Design:

Randomized, placebo-controlled, double-blind, cross-over study with 3 study-days, separated by 7-day intervals.

Patients:

The study will be carried out in 12 patients 18 - 70 years of age, with an established diagnosis of T2DM treated by oral anti-diabetic therapy for at least 3 years.

Treatments:

Patients will receive a freshly prepared drink containing 25 or 50 g of carbohydrate (50% glucose and 50% maltodextrin) with 10 g hydrolysate or 50 g without Hydrolysate as a negative control.
Drinks will be flavored by adding 0.2 g sodium saccharinate, 1.8 g citric acid, and 5 g cream vanilla flavor (Quest International) per liter of beverage.

Study parameters:

Serum concentrations and AUC of glucose and insulin.

Study objective

10 grams of a hydrolysate effectively increase insulin secretion and lowers plasma glucose levels after a 25 or 50 grams carbohydrate load in type 2 diabetes mellitus (DM-2)

Study design

Baseline, 15, 30, 45, 60, 90 and 120 min.

Intervention

The treatments will consist of a drink that will be freshly prepared prior to use. The drink will be administered as a single oral bolus (300 mL) containing 25 or 50 g of carbohydrate (50% glucose and 50% maltodextrin) with 10 g Hydrolysate.

Contacts

Public
Department of Endocrinology
Leiden University Medical Center

J.W.A. Smit
Leiden
The Netherlands
Scientific
Department of Endocrinology
Leiden University Medical Center

J.W.A. Smit
Leiden

The Netherlands

Eligibility criteria

Inclusion criteria

1. Males or females, 18-70 years old.

2. Fasting glucose level > 7 mmol/L after 2 days refraining from medication.

3. Are on stable medication with biguanides for at least 3 months.

4. Prepared and able to give written informed consent;

Exclusion criteria

1. Use of insulin, sulfonylurea derivatives, meglitinides or other antidiabetic drugs except biguanides.

2. BMI > 35 kg/m2.

3. Females who are pregnant, have the intention to become pregnant within the study period, or who are lactating.

4. A present and clinically significant history of ischemic heart disease (such as angina pectoris with an incidence of more than one attack/month), acute myocardial infarction within one year prior to the study or congestive heart failure (defined as NYHA class III or IV).

5. Uncontrolled hypertension.

6. Active, proliferative retinopathy

7. Active or history of liver disease or impaired renal function (defined as a creatinin clearance calculated with the Cockcroft-Gault formula below 60 ml/min).

8. Participation in a trial within 3 months prior to the start of the study or more then 4 times a year.

9. Loss of 250 ml or more of blood within 3 months prior to screening.

10. Any clinical condition, including use of co-medication or laboratory test results that in the opinion of the investigators may jeopardize the health status of the participants.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2008
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-02-2008
Application type:	First submission

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
NTR-new	NL1193
NTR-old	NTR1238
Other	MEC LUMC : P07200-2
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A