Effects of 5 or 10 gram of the protein hydrolysate InsuVital* on serum insulin and glucose levels in patients with type 2 diabetes mellitus and the influence of varying carbohydrate loads

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Part I: The objective of Part I of this study is the efficacy of a single 5-g and 10-g dose of InsuVital* on blood levels of insulin and glucose in patients with T2DM.Part II: The objective of Part II of this study is to assess the effect of a 10-g...

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

Summary

ID

NL-OMON32298

Source
ToetsingOnline

Brief title
Low dose InsuVital in type 2 Diabetes Mellitus

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes mellitus type 2

Research involving
Human

Sponsors and support

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

Intervention

Keyword: insuvital, protein hydrolysate, type 2 diabetes mellitus

Outcome measures

Primary outcome

Serum concentrations and AUC of glucose and insulin.

Secondary outcome

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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 (InsuVital*). 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 carried out with a relatively high dose of protein. Hence, information on interventions with a lower protein load is necessary.
Part I of the current study will address the efficacy of 5 and 10 g of InsuVital in lowering blood levels of insulin and glucose in patients with type 2 diabetes mellitus (T2DM).
Previous experiments were also carried out with a high dose of carbohydrate. It is not known if InsuVital* is efficacious in the presence of lower carbohydrate doses.
Part II of the current study will therefore address the efficacy of a fixed dose of InsuVital, combined with either a low or a high carbohydrate load in lowering blood levels of insulin and glucose in patients with T2DM.

Study objective

Part I: The objective of Part I of this study is the efficacy of a single 5-g

and 10-g dose of InsuVital* on blood levels of insulin and glucose in patients with T2DM.
Part II: The objective of Part II of this study is to assess the effect of a 10-g dose of InsuVital* 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.

Intervention

Part I: 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 50 g of carbohydrate (50% glucose and 50% maltodextrin) with 0, 5, or 10 g InsuVital*.
Part II: Patients will receive a freshly prepared drink containing 25 or 50 g of carbohydrate (50% glucose and 50% maltodextrin) with 10 g InsuVital*or 50 g without InsuVital* 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 burden and risks

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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

• Males or females, 18-70 years old.
• Fasting glucose level > 7 mmol/L after 2 days refraining from medication.
• Are on stable medication with biguanides for at least 3 months.
• Prepared and able to give written informed consent;

Exclusion criteria

• Use of insulin, sulfonylurea derivatives, meglitinides or other antidiabetic drugs except biguanides;
• BMI > 35 kg/m2;
• Females who are pregnant, have the intention to become pregnant within the study period, or who are lactating;
• 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);
• Uncontrolled hypertension;
• Active, proliferative retinopathy
• 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);
• Participation in a trial within 3 months prior to the start of the study or more then 4 times a year;
• Loss of 250 ml or more of blood within 3 months prior to screening;
• 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:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2008
Enrollment:	24
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL19875.058.07