A study on the effects on plasma insulin and glucose after a single meal replacement (InsuVital) with or without added Leucine in patients with T2DM

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Objectives:To assess the effect of a single meal replacement (InsuVital®) with or without added leucine on blood levels of insulin, C-peptide and glucose in patients with T2DM.

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

Summary

ID

NL-OMON31143

Source
ToetsingOnline

Brief title
Single dose InsuVital in T2DM

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, glucose intolerance

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Diabetes Mellitus, Meal replacement

Outcome measures

Primary outcome

Main Parameters:

Serum concentrations and AUC of glucose, insulin, and C-peptide.

Secondary outcome

na

Study description

Background summary

Rationale:
There is accumulating evidence that amino acids such as leucine play a role as insulin secretagogues. One of possible clinical application that is currently explored is a mixture of protein hydrolysate and an amino acid mixture (InsuVital®). Research with this product has shown that co-ingestion of this product with carbohydrate augments the insulin response and enhances glucose disposal. These effects are observed in patients with both a recent and long-standing diagnosis of T2DM. However, previous experiments were carried out with a relatively high dose of protein that may be potentially detrimental for the renal function in T2DM patients, especially when the product is used chronically. Hence, information on interventions with a lower protein load is necessary. Therefore a study will be performed with the product in a relatively low dose with or without added leucine on blood levels of insulin and glucose in diabetic subjects.

Study objective

Objectives:
To assess the effect of a single meal replacement (InsuVital®) with or without added leucine on blood levels of insulin, C-peptide and glucose in patients with T2DM.

Study design

Study Design:
Randomized, placebo-controlled, double-blind, partial cross-over study in which each participant will receive three of four possible treatments

Intervention

Treatments:
The treatments will consist of a drink (shake) that will be freshly prepared prior to use. The composition of the 4 possible treatments is:
1. Carbohydrate / Fat / Vitamins & minerals
2. Carbohydrate / Fat / Vitamins & minerals / Unhydrolysed protein
3. Carbohydrate / Fat / Vitamins & minerals / InsuVital / Chromium
4. Carbohydrate / Fat / Vitamins & minerals / InsuVital / Leucine / Chromium
For each of the treatments the amount of Carbohydrate, Fat and Vitamins & minerals will be identical. Also, the amount of InsuVital used in the preparations for which this is applicable will be the same.

Study burden and risks

Procedures (outlay):
Potential participants will be recruited using the CHDR database, contacts with dept of Endocrinology of LUMC and general practioners and advertisements. After an information session and upon providing informed consents patients will be medically screened. When no objections against participation in the study can be identified during the screening the patients will be invited to visit CHDR 3 times, with each visit separated by at least 7 days. At each visit they will be given one of the study treatments and blood sampling for glucose metabolism will take place for a period of 4 hours.

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

adults
>= 1 year oral anti-diabetic medication

Exclusion criteria

insulin use
significant diabetes complications

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2007
Enrollment:	36
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	NL17059.058.07
Other	volgt 9 3 07