A study on the effects on plasma insulin and glucose after a single meal replacement in patients with T2DM.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29176

Source
Nationaal Trial Register

Brief title
N/A

Health condition

diabetes / insulin response

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Insulin and glucose response.

Secondary outcome

Hormones involved in glucose homeostasis.

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. 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.
The treatments will consist of drinks that will be freshly prepared prior to use. There are four possible treatments with a different composition of protein.
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.

Study objective

A single oral doses of amino acids may play a role as insulin secretagogues.

Study design

N/A

Intervention

Intervention with single meals with different composition of amino acids in a double-blind placebo controlled trial.

Contacts

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Eligibility criteria

Inclusion criteria

Adult T2DM patients.

Exclusion criteria

1. Insulin use;

2. Significant clinical abnormalities.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2007
Enrollment:	36
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

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	NL918
NTR-old	NTR942
Other	: N/A
ISRCTN	ISRCTN48222371

Study results

Summary results
N/A