

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

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

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29176

Bron

Nationaal Trial Register

Verkorte titel

N/A

Aandoening

diabetes / insulin response

Ondersteuning

Primaire sponsor: DSM

Overige ondersteuning: DSM

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Insulin and glucose response.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adult T2DM patients.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Insulin use;
2. Significant clinical abnormalities.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2007
Aantal proefpersonen:	36
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL918
NTR-old	NTR942
Ander register	: N/A
ISRCTN	ISRCTN48222371

Resultaten

Samenvatting resultaten

N/A