

# A study on the effects on plasma insulin and glucose after a single meal replacement in patients with type two diabetes mellitus

**Submission date**  
02/05/2007

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
02/05/2007

**Overall study status**  
Completed

☐ Statistical analysis plan

☐ Results

**Last Edited**  
10/03/2008

**Condition category**  
Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr J. Burggraaf

### Contact details

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Zernikedreef 10  
Leiden  
Netherlands  
2333 CL

## Additional identifiers

### Protocol serial number

N/A

## Study information

### Scientific Title

### Study objectives

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

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised, double blinded, placebo controlled crossover trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Diabetes, insulin response

**Interventions**

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

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Plasma insulin, glucose

**Primary outcome(s)**

Insulin and glucose response

**Key secondary outcome(s)**

Hormones involved in glucose homeostasis

**Completion date**

01/09/2007

## **Eligibility**

**Key inclusion criteria**

Adult Type two Diabetes Mellitus (T2DM) patients

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Not Specified

**Key exclusion criteria**

1. Insulin use
2. Significant clinical abnormalities

**Date of first enrolment**

01/04/2007

**Date of final enrolment**

01/09/2007

**Locations****Countries of recruitment**

Netherlands

**Study participating centre**

Center for Human Drug Research

Leiden

Netherlands

2333 CL

**Sponsor information****Organisation**

Dutch State Mines (DSM) (The Netherlands)

**ROR**

<https://ror.org/00k01kt20>

**Funder(s)****Funder type**

Industry

**Funder Name**

Dutch State Mines (DSM) (The Netherlands)

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes