

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

Study website

<http://www.chdr.nl>

Contact information

Type(s)

Scientific

Contact name

Dr J. Burggraaf

Contact details

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Netherlands
2333 CL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

Insulin and glucose response

Secondary outcome measures

Hormones involved in glucose homeostasis

Overall study start date

01/04/2007

Completion date

01/09/2007

Eligibility

Key inclusion criteria

Adult Type two Diabetes Mellitus (T2DM) patients

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

36

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)

Sponsor details

P.O. Box 6500

Heerlen

Netherlands

6401 JH

Sponsor type

Industry

Website

http://www.dsm.com/en_US/html/about/about_us_home.htm

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Dutch State Mines (DSM) (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration