Effect of a new disease-specific enteral formula on metabolic control in type 2 diabetic patients.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21914

Source
NTR

Brief title
Diacarb trial

Health condition

Diabetes Mellitus type 2 (DM type II)

Sponsors and support

Primary sponsor: Numico Research B.V.
Source(s) of monetary or material Support: Numico Research B.V.

Intervention

Outcome measures

Primary outcome

HbA1c

Secondary outcome

1. Fasting plasma glucose

2. Fasting plasma insulin

3. Fructosamine

4. Fasting plasma lipid profile:

Triglycerides, Total cholesterol, LDL, HDL

5. Fasting free fatty acids (FFA)

6. Total daily insulin requirement

7. Insulin sensitivity by HOMA-IR

8. Incidence of skin, pulmonary and urinary tract infections

9. Fasting (hs) CRP

10. Fasting pro-inflammatory cytokines: IL-6, IL-8, IL-18, and TNF-¨¢

11. Fasting plasminogen activator inhibitor-1 activity (PAI-1)

12. Blood pressure

13. Tolerance

Study description

Background summary

In this trial disease-specific formula will be compared with an isocarloric standard enteral formula with fibre on HbA1c in diabetic patients.

Study objective

To determine the effect on HbA1c of a disease-specific enteral formula compared to an isocaloric standard enteral formula (control) in type 2 diabetic patients after 12 weeks of supplementation.

Intervention

Duration intervention: 12 weeks Intervention group: diabetic specific enteral formula Control

group: isocaloric standard enteral formula with fibre

Contacts

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Eligibility criteria

Inclusion criteria

1. Type 2 diabetic patients

2. Diagnosis of type 2 diabetes according to WHO criteria for more than 6 months

3. Age >18

4. Hospitalised patients, patients in nursing homes or home-care patients

5. HbA1c between 6.1%-10,5% (including 6,1% and 10.5%)

6. 18 kg/m2 ¡Ü BMI ¡Ü 35 kg/m2

7. Indication for tube feeding for at least 6 weeks

8. Functioning GI tract, eligible for tube feeding

9. Nutrition via PEG or nasogastric tube

10. Willing to comply with the study protocol

11. Signed informed consent

Exclusion criteria

1. Any gastrointestinal disease that interferes with bowel function and nutritional intake (i.e. diabetes related constipation/diarrhea secondary to neuropathy, diarrhea due to chronic inflammatory bowel disease, gastroparesis, gastrectomy)

2. Concomitant intake of parenteral nutrition or other clinical enteral nutrition

3. Significant heart (NYHA class IV), hepatic (transaminase more than 3 times normal) or renal disease (requiring dialysis)

4. Concomitant therapy with acarbose

5. Concomitant therapy with systemic glucocorticoids or within 2 weeks prior to study entry

6. Nutrition via any tube that has to be placed into the jejunum

7. Galactosaemia

8. Alcohol abuse

9. Investigator's uncertainty about the willingness or ability of the patient to comply with the protocol requirements

10. Participation in other studies within 4 weeks of study entry

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2006
Enrollment:	140
Type:	Anticipated

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	NL757
NTR-old	NTR768
Other	: N/A
ISRCTN	ISRCTN32726656

Study results

Summary results

N/A