

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

Submission date

28/12/2006

Recruitment status

No longer recruiting

Registration date

28/12/2006

Overall study status

Completed

Last Edited

22/09/2021

Condition category

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☐ Results

☐ 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NL757 (NTR768)

Study information

Scientific Title

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

Acronym

Diacarb trial

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the local ethics board (Stichting beoordeling Ethiek Biomedisch Onderzoek [BEBO]) on the 3rd April 2007 (ref: X115).

Study design

Randomised controlled, parallel group, double blinded, multicentre 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 Mellitus type two (DM type II)

Interventions

Duration intervention: 12 weeks

Intervention group: diabetic specific enteral formula

Control group: isocaloric standard enteral formula with fibre

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

HbA1c

Secondary outcome measures

1. Fasting plasma glucose
2. Fasting plasma insulin
3. Fructosamine
4. Fasting plasma lipid profile:
 - a. Triglycerides
 - b. Total cholesterol
 - c. Low Density Lipoprotein (LDL)
 - d. High Density Lipoprotein (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) C-Reactive Protein (CRP)
10. Fasting pro-inflammatory cytokines: Interleukin -6 (IL-6), Interleukin-8 (IL-8), and Tumour Necrotising Factor (TNF)
11. Fasting Plasminogen Activator inhibitor-1 activity (PAI-1)
12. Blood pressure
13. Tolerance

Overall study start date

01/11/2006

Completion date

01/09/2008

Eligibility

Key inclusion criteria

1. Type two diabetic patients
2. Diagnosis of type two diabetes according to World Health Organisation (WHO) criteria for more than six months
3. Aged over 18
4. Hospitalised patients, patients in nursing homes or home-care patients
5. HbA1c between 6.1% and 10.5% (including 6.1% and 10.5%)
6. Body Mass Index (BMI) between 18 kg/m² and 35 kg/m²
7. Indication for tube feeding for at least six weeks
8. Functioning GastroIntestinal (GI) tract, eligible for tube feeding
9. Nutrition via Percutaneous Endoscopic Gastrostomy (PEG) or nasogastric tube
10. Willing to comply with the study protocol
11. Signed informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

140

Key exclusion criteria

1. Any gastrointestinal disease that interferes with bowel function and nutritional intake (i.e. diabetes related constipation/diarrhoea secondary to neuropathy, diarrhoea due to chronic inflammatory bowel disease, gastroparesis, gastrectomy)
2. Concomitant intake of parenteral nutrition or other clinical enteral nutrition
3. Significant heart (New York Heart Association [NYHA] class IV), hepatic (transaminase more than three times normal) or renal disease (requiring dialysis)
4. Concomitant therapy with acarbose
5. Concomitant therapy with systemic glucocorticoids or within two 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 four weeks of study entry

Date of first enrolment

01/11/2006

Date of final enrolment

01/09/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Numico Research B.V.

Amsterdam

Netherlands

1118 ZN

Sponsor information

Organisation

Numico Research B.V. (The Netherlands)

Sponsor details

P.O. Box 7005
Wageningen
Netherlands
6700 CA

Sponsor type

Industry

Website

<http://www.numico.com/en/>

ROR

<https://ror.org/00aj77a24>

Funder(s)**Funder type**

Industry

Funder Name

Numico Research B.V. (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