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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	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 28/12/2006	**Overall study status** Completed	
Last Edited 22/09/2021	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 HOmeostatic Model Assessment (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/m^2 and 35 kg/m^2
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.
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Sponsor information

Organisation
Numico Research B.V. (The Netherlands)

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P.O. Box 7005
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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