ISRCTN32726656 https://doi.org/10.1186/ISRCTN32726656

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

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 28/12/2006 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 28/12/2006 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 22/09/2021 | Nutritional, Metabolic, Endocrine | [ ] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr M de Vries

**Contact details**
Numico Research B.V.
Postbus 75538
Amsterdam
Netherlands
1118 ZN
+31 (0)31 746 7800
Miranda.deVries@numico-research.nl

## Additional identifiers

**Protocol serial number**
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).

## Primary study design
Interventional

## Study design
Randomised controlled, parallel group, double blinded, multicentre trial

## Study type(s)
Treatment

## 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(s)
HbA1c

## Key secondary outcome(s)
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
Not Specified

### 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)

### ROR
https://ror.org/00aj77a24

## Funder(s)

### Funder type

Industry

**Funder Name**
Numico Research B.V. (The Netherlands)

# Results and Publications

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Not provided at time of registration