# ESPRIT study

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A 4 hour intervention period with the new disease-specific tube feed will result in a better plasma glucose profile as compared to an isocaloric standard tube feed.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestopt |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON26603

**Bron**
NTR

**Verkorte titel**
ESPRIT study

**Aandoening**

type 2 diabetes
type 2 diabetes patients
plasma glucose profile
tube feed
disease-specific
DM II

### Ondersteuning

**Primaire sponsor:** Danone Research ¨C Centre for Specialised Nutrition
**Overige ondersteuning:** Danone Research ¨C Centre for Specialised Nutrition

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Plasma glucose as assessed with the increase from baseline in plasma glucose levels in the t=3-4 hours period<br>

# Toelichting onderzoek

### Achtergrond van het onderzoek

In this study the plasma glucose profile of a new disease-specific tube feed for type 2 diabetes patients will be compared to a standard tube feed in 24 ambulant type 2 diabetes patients. The study is performed in 1 centre in the Netherlands.

### Doel van het onderzoek

A 4 hour intervention period with the new disease-specific tube feed will result in a better plasma glucose profile as compared to an isocaloric standard tube feed.

### Onderzoeksopzet

Time points of the outcome: V0 (screening ¨C 3 wks); Day 1 (day 1); Day 2 (4-10 days); FU cal (+ 3 days).

### Onderzoeksproduct en/of interventie

Duration of intervention:2 times 4 hours of continuous feeding

Intervention group: Nutrison Advanced Diason Energy HP

Control group: Nutrision Energy MF

# Contactpersonen

## Publiek

Danone Research - Centre for Specialised Nutrition<br>
Bosrandweg 20
Mirian Lansink
Wageningen 6700 CA
The Netherlands
+31 (0)317 467814

### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age/sex: males (age >= 18 yrs) or post-menopausal females

- Ambulant type 2 diabetes patients

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

- BMI 35 kg/m2

- HbA1c <7.5%

- Functioning gastrointestinal tract, eligible for tube feeding via a nasogastric tube

- A stable and controlled anti-hyperglycaemic therapy with metformin and/or sulfonylureum for at least two months; regimes are expected to remain stable throughout the duration of the study

- Willingness to comply with the study protocol, including:

- Overnight stay and fast (at least 10 hours) before each study visit

- Refrain from alcohol consumption (24h) and intense physical activities (48h) prior to and during the assessments

- Not changing dietary and smoking habits for the duration of the study

- Written informed consent

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

- Known heart failure, defined by New York Heart Association (NYHA) class IV

- Kidney disease, defined by serum creatinine > 160 ¦Ìmol/L (1.8 mg/dL) or requiring dialysis

- Hepatic disease, defined by transaminases (ALAT, ASAT, or alkaline phosphatase) levels more than 5 times upper limit of normal

- Severe anemia (hemoglobin ¡Ü5 mmol/L or 8 g/dl)

- Major infections (requiring antibiotics) within 2 weeks prior to study entry
- Concomitant therapy with alpha-glucosidase inhibitors (acarbose), meglitinides, thiazolidinediones, peptide analogues (GLP antagonisten) or insulin

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

- Concomitant therapy with beta-blockers

- Subjects requiring a fibre-free diet

- Galactosaemia

- Alcohol abuse

- History of allergy or intolerance to the study product components (test or control product)

- Investigator's uncertainty about the willingness or ability of the subject to comply with the protocol requirements

- Participation in any other studies involving investigational or marketed products concomitantly within 6 weeks of study entry

# Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Cross-over |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Dubbelblind |
| Controle: | Geneesmiddel |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 12-09-2013 |
| Aantal proefpersonen: | 24 |
| Type: | Werkelijke startdatum |

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 06-09-2013 |
| Soort: | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID |
|---|---|
| NTR-new | NL3991 |

| Register | ID |
| --- | --- |
| NTR-old | NTR4163 |
| Ander register | Danone Research : NTS.6.C/A |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Resultaten

**Samenvatting resultaten**
N/A