# ESPRIT study

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON26603

**Source**
NTR

**Brief title**
ESPRIT study

**Health condition**

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

### Sponsors and support

**Primary sponsor:** Danone Research ¨C Centre for Specialised Nutrition
**Source(s) of monetary or material Support:** Danone Research ¨C Centre for Specialised Nutrition

### Intervention

### Outcome measures

**Primary outcome**

Plasma glucose as assessed with the increase from baseline in plasma glucose levels in the

t=3-4 hours period

### Secondary outcome

- Glucose profile as assessed with:

o iAUC mean glucose

o (delta) peak glucose

o difference between max-min glucose value

o decline in glucose levels after stop tube feeding

o incidence of hyperglycaemia (>10 mmol/L)

o incidence of hypoglycaemia (<3.9 mmol/L)

o AUC above cut-off lines of 10 mmol/L

o AUC beneath cut-off lines of 3.9 mmol/L

- Insulin

## Study description

### Background summary

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.

### Study objective

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.

### Study design

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

### Intervention

Duration of intervention:2 times 4 hours of continuous feeding

Intervention group: Nutrison Advanced Diason Energy HP

Control group: Nutrision Energy MF

# Contacts

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# Eligibility criteria

## Inclusion criteria

- 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

## Exclusion criteria

- 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

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Crossover |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Active |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 12-09-2013 |
| Enrollment: | 24 |
| Type: | Actual |

# Ethics review

Positive opinion

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|---|---|
| Date: | 06-09-2013 |
| Application type: | First submission |

# 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 | NL3991 |
| NTR-old | NTR4163 |
| Other | Danone Research : NTS.6.C/A |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
N/A