The effect of a protein/fibre drink on postprandial glycaemic metabolism in type 2 Diabetes Mellitus.

No registrations found.

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

Summary

ID

NL-OMON29557

Source
NTR

Brief title
GRACE: glucose reduction after caloric exposure

Health condition

type 2 diabetes mellitus

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

Postprandial blood glucose responses to a Meal Tolerance Test.

Secondary outcome

The effect of the study product on satiety.

Study description

Background summary

The purpose of this study is to assess
the effect of the study product (a protein and fibre-rich drink) on postprandial glycaemic responses, satiety, ¦Â-cell function and insulin sensitivity in type 2 diabetes mellitus. It is expected that the drink will contribute to an improved postprandial glycaemic response and to an increase of satiety in subjects
with type 2 diabetes mellitus.

Study objective

It is expected that the drink will contribute to an improved postprandial glycaemic response and to an increase of satiety in subjects with type 2 diabetes mellitus.

Study design

Two study periods (cross-over) from day 1 - 8 with 2-3 week wash out in between. On day 1 and 8 study visits will take place to measure postprandial glycaemic response and satiety. During the study periods, study product will be used bi-daily.

Intervention

Intake of study product.

Duration of intervention: Approximately one month; one week on first study product followed by a 2-3 week wash out period and one week on the second studyproduct.

Intervention group: Type 2 Diabetes patients.

All included subjects will be treated with both the placebo and active product, in random order (cross-over study). Both study periods have a duration of 8 days in which the subjects consume 2 tetra packs of study product per day. There is a wash out period of 2 to 3 weeks in between the studyperiods. A study visit will take place at the first and last day of each studyperiod. During these visits blood will be drawn for examination of glucose responses. Each visit will take approx. 4.5

hours.

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Eligibility criteria

Inclusion criteria

1. Written informed consent;

2. Age > 45 years;

3. Women: postmenopausal;

4. 25 < BMI > 35 kg/m2;

5. Type 2 diabetes mellitus with an HbA1C > 6.0 and < 8, preferably >6.4 and < 8, stable for the past 3 months as judged by the investigator;

6. No antidiabetic medication (i.e. sulphonylureas, insulin treatment) with the exemption of a stable and controlled anti-diabetic regime with metformin for at least 2 months and maximally 2000 mg/day and expected to remain stable throughout the duration of the study;

7. Willing to comply with the study protocol.

Exclusion criteria

1. On a weight loss diet;

2. Any gastrointestinal disease that interferes with bowel function and nutritional intake (i.e. diabetes related constipation or diarrhoea secondary to neuropathy, diarrhoea due to chronic inflammatory bowel disease, gastroparesis, (partial) gastrectomy or any other procedure for stomach volume reduction, including gastric banding);

3. Significant heart (NYHA class IV), pulmonary, hepatic (transaminase greater than 3 times normal), renal disease (requiring dialysis or creatinine >150 µmol/l) or metabolic disorders;

4. Uncontrolled thyroid and/or adrenal disease, interfering malignant or haematological diseases;

5. Blood pressure > 160/90 mmHg , severe dyslipidemia (cholesterol > 8 mmol/l, triglycerides > 4 mmol/l);

6. Major infections (requiring antibiotics) within 3 weeks prior to study entry;

7. Concomitant therapy with sulfonylurea derivatives, acarbose, meglitinides, DPP-IV inhibitors, thiazolidinediones or insulin;

8. The use of drugs: all drugs that affect insulin secretion or insulin sensitivity, drugs or supplements that affect stomach pH, intestinal absorption and intestinal motility, moreover all concomitant medication should be discussed, in particular antiviral, oestrogens, progestagens, androgens, thiazide diuretics and anti-psychotic drugs;

9. Concomitant therapy with systemic glucocorticoids within 2 weeks prior to study entry;

10. Requirement of a fibre-free diet;

11. Alcohol intake of more than 21 alcohol containing drinks per week for men and 14 for women and the use of other drugs (e.g. marihuana and other soft drugs);

12. Investigator's uncertainty about the willingness or ability of the patient to comply with the protocol;

13. Participation in other clinical trials within 4 weeks of study entry.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-04-2009
Enrollment:	36
Type:	Actual

Ethics review

Positive opinion

Date:	06-02-2009
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	NL1582

Register	ID
NTR-old	NTR1662
Other	METC VUmc : 09/012
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A