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

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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.

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

Samenvatting

ID

NL-OMON29557

Bron
Nationaal Trial Register

Verkorte titel
GRACE: glucose reduction after caloric exposure

Aandoening

type 2 diabetes mellitus

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

Postprandial blood glucose responses to a Meal Tolerance Test.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	28-04-2009
Aantal proefpersonen:	36
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	06-02-2009
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	NL1582

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

Resultaten

Samenvatting resultaten
N/A