Effect of a diabetes-specific oral nutritional supplement (ONS) vs. standard ONS on the postprandial glucose response in adults with type 2 diabetes with (risk of) malnutrition.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24556

Source
Nationaal Trial Register

Brief title
CareFull

Health condition

Diabetes Mellitus type 2

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

4-hour postprandial blood glucose response after consumption of diabetes-specific or standard ONS (iAUC0-4h).

Secondary outcome

1. 4-hour postprandial responses after consumption of diabetes-specific or standard ONS:

A. Blood glucose levels (iAUC0-4h) (serving size);

B. Blood insulin levels (iAUC0-4h);

C. Blood glucagon levels (iAUC0-4h).

2. Postprandial peak blood glucose, insulin and glucagon levels;

3. Postprandial delta peak blood glucose, insulin and glucagon levels.

Study description

Background summary

In this study the effect of a diabetes-specific oral nutritional supplement (ONS) on the 4-hour postprandial glucose response will be compared to a standard ONS in adults with type 2 diabetes with (risk of) malnutrition.

Study objective

Diabetes specific oral nutritional supplement has an improved 4-hour postprandial glucose response compared to standard oral nutritional supplement.

Study design

Screening, Baseline, Day 1, Day 2, Day 3, Follow up.

Intervention

Duration of intervention: 3 days.

Intervention group: A high-energy, high-protein diabetes-specific ONS.

Control group: An isocaloric high-energy, high-protein ONS.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age ≥ 18 yrs;

2. (At risk of) malnourishment, based on the presence of one or more of the following criteria:

A. ≥ 5% involuntary weight loss in the last month, or;

B. ≥ 10% involuntary weight loss in the last 6 months, or;

C. Serum albumin < 35 g/L, or;

D. Age ≥ 70 yrs and body mass index (BMI) < 21.0 kg/m2, or;

D. Age < 70 yrs and BMI < 18.5 kg/m2, or;

E. Age ≥ 65 yrs and Short Mini Nutritional Assessment (MNA) score ≤ 11.

3. Diagnosis of type 2 diabetes for at least six months;

4. On stable (20%) anti-hyperglycaemic therapy (oral medication and/or insulin) for at least 1 month prior to study entry;

5. Willingness and ability to comply with the study protocol, including: An overnight fast (at least 10 hours) at each study day.

6. Written informed consent.

Exclusion criteria

1. Any gastrointestinal disease that interferes with bowel function and nutritional intake (i.e. diabetes related diarrhoea secondary to neuropathy, diarrhoea due to chronic inflammatory bowel disease, gastroparesis);

2. Any known severe disease, i.e.:

A. Heart failure (New York Heart Association (NYHA) class IV);

B. Kidney disease (Chronic Kidney Disease (CKD) ≥ stage 4);

C. Hepatic disease (transaminases > 5 times upper limit of normal);

D. Severe anemia (hemoglobin <8 g/dl or 5 mmol/L).

3. (Metabolic) disorders interfering with stable glucose metabolism (i.e. uncontrolled thyroid and/or adrenal disease, or interfering malignant diseases);

4. Concurrent condition /treatment that interferes with stable glucose metabolism (i.e. immediately post-operative);

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

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

7. Pregnant female;

8. Requirement of a fibre-free diet;

9. Intolerance or allergy to dairy or other ingredients of the study products;

10. Alcohol intake of > 21 units per week for men and > 14 units per week for women;

11. Swallowing disorders making consumption of an oral nutritional supplement impossible;

12. Parenteral feeding / tube feeding;

13. Investigators' uncertainty about the willingness or ability of the subject to comply with the protocol requirements;

14. Participation in any other studies involving investigational or marketed products concomitantly or within 4 weeks prior to entry into the study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-12-2012
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-12-2012
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	NL3576
NTR-old	NTR3734
Other	Danone Research : Dia.6.C/A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A