The effect of a disease-specific supplement on the postprandial plasma glucose response in type 2 diabetic patients at baseline and after 6 and 12 weeks of supplementation.

No registrations found.

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

Summary

ID

NL-OMON23712

Source
NTR

Brief title
DiaDrink trial

Health condition

Type 2 diabetic patients in need of nutritional support.

Sponsors and support

Primary sponsor: Numico Research B.V.
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Intervention

Outcome measures

Primary outcome

Postprandial glucose response.

Secondary outcome

1. Glycaemic control before and after 6 and 12 weeks of supplementation;

2. Fasting plasma lipid profile before and after 6 and 12 weeks of supplementation.

Study description

Background summary

In this trial disease specific sipfeed will be compared with standard sipfeed on glucose control in diabetic patients.

Study objective

Usage of disease specific sip feed will improve glucose control in diabetic patients.

Study design

N/A

Intervention

Duration intervention: 12 weeks
Intervention group: disease specific sipfeed.

Control group: isocaloric standard sipfeed.

Contacts

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Eligibility criteria

Inclusion criteria

1. Diagnosis type 2 diabetes;

2. Age > 18;

3. HbA1c between 6.5%-8.5%;

4. Anti-diabetic therapy: Metformin and/or sulfonylureas;

5. In need of nutritional support;

6. Capable of using oral drink feed supplementation;

7. On a stable and controlled anti-diabetic regime for at least one month;

8. Signed informed consent.

Exclusion criteria

1. Pregnant or lactating woman or woman planning to become pregnant;

2. Usage of a disease specific nutritional supplement within past 4 weeks;

3. Concomitant therapy with systemic glucocorticoids, insulin or anti-diabetic medication other than Metformin or sulfonylureas;

4. Any acute gastrointestinal disease within 2 weeks prior to study entry;

5. Gastrectomy, gastroparesis or other gastric emptying abnormalities;

6. Acute severe heart failure, end stage liver failure or renal failure requiring dialysis;

7. Patients receiving enteral nutrition;

8. Patients with galactosaemia, fructosaemia or patients requiring a fibre free diet;

9. Drug or alcohol abuse;

10. Participation in other trials within 4 weeks of study entry.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-12-2005
Enrollment:	34
Type:	Actual

Ethics review

Positive opinion

Date:	12-04-2006
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	NL597
NTR-old	NTR653
Other	: 100015
ISRCTN	ISRCTN86065299

Study results

Summary results

Diabetes Res Clin Pract. 2008 Apr;80(1):75-82. Epub 2007 Dec 11.