

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

Submission date 07/06/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/06/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/01/2021	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Carlette Rouws

Contact details
Numico Research B.V.
P.O. Box 7005
Wageningen
Netherlands
6700 CA
+31 (0)31 7467972
carlette.rouws@numico-research.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

100015, NL597, NTR653

Study information

Scientific Title

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

Acronym

DiaDrink trial

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Diabetes Mellitus type II (DM type II)

Interventions

Duration intervention: 12 weeks

Intervention group: disease-specific sip feed.

Control group: isocaloric standard sip feed.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Postprandial glucose response.

Secondary outcome measures

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

Overall study start date

15/12/2005

Completion date

01/09/2006

Eligibility

Key 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

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

34

Total final enrolment

40

Key exclusion criteria

1. Pregnant or lactating woman or woman planning to become pregnant
2. Usage of a disease-specific nutritional supplement within past four weeks
5. Concomitant therapy with systemic glucocorticoids, insulin or anti-diabetic medication other than metformin or sulfonylureas

6. Any acute gastrointestinal disease within two weeks prior to study entry
7. Gastrectomy, gastroparesis or other gastric emptying abnormalities
8. Acute severe heart failure, end stage liver failure or renal failure requiring dialysis
9. Patients receiving enteral nutrition
10. Patients with galactosaemia, fructosaemia or patients requiring a fibre-free diet
11. Drug or alcohol abuse
12. Participation in other trials within 4 weeks of study entry

Date of first enrolment

15/12/2005

Date of final enrolment

01/09/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

Numico Research B.V.

Wageningen

Netherlands

6700 CA

Sponsor information

Organisation

Numico Research B.V. (The Netherlands)

Sponsor details

P.O. Box 7005

Wageningen

Netherlands

6700 CA

Sponsor type

University/education

ROR

<https://ror.org/00aj77a24>

Funder(s)

Funder type

Industry

Funder Name

Numico Research B.V.

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2008	08/01/2021	Yes	No