ISRCTN86065299 https://doi.org/10.1186/ISRCTN86065299

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

Registration date
07/06/2006

Overall study status
Completed

Last Edited
08/01/2021

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
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

Study type(s)
Treatment

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(s)
Postprandial glucose response.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

ROR
https://ror.org/00aj77a24

Funder(s)

Funder type
Industry

Funder Name
Numico Research B.V.

Results and Publications

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