

The effect of nutritional supplementation with a disease specific tube feed on the postprandial plasma glucose response in type 2 diabetic patients at baseline and after 6 and 12 weeks of supplementation

Submission date

08/03/2006

Recruitment status

No longer recruiting

Registration date

08/03/2006

Overall study status

Completed

Last Edited

24/08/2009

Condition category

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

NTR584; 100088

Study information

Scientific Title

Acronym

DiaTube trial

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Primary study design

Interventional

Study design

Multicentre randomised double blind active controlled parallel group trial

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 tube feed

Control group: isocaloric standard tube 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. In need of nutritional support by tube feeding for at least 12 weeks
5. Functioning gastrointestinal (GI) tract, eligible for tube feeding
6. Nutrition via percutaneous endoscopic gastrostomy (PEG) or nasogastric tube
7. Having given written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Pregnant or lactating women or women planning to become pregnant
2. Usage of a disease specific tube feed within past 4 weeks
3. Acute severe heart failure, end stage liver failure or renal failure requiring dialysis;
4. Any acute gastrointestinal disease within past 2 weeks
5. Concomitant therapy with glucocorticoids or acarbose
6. Nutrition via percutaneous endoscopic jejunostomy (PEJ)
7. Drug or alcohol abuse
8. Participation in other trials within four weeks of study entry

Date of first enrolment

01/01/2006

Date of final enrolment

01/09/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

Numico Research
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. (Netherlands)

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	01/10/2009		Yes	No