ISRCTN57864852 https://doi.org/10.1186/ISRCTN57864852

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	Recruitment status
08/03/2006	No longer recruiting
Registration date	**Overall study status**
08/03/2006	Completed
Last Edited	**Condition category**
24/08/2009	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Multicentre randomised double blind active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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 tube feed
Control group: isocaloric standard tube 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
01/01/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
58

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)

Sponsor details
P.O. Box 7005
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Sponsor type
Not defined

ROR
https://ror.org/00aj77a24

Funder(s)

Funder type
Industry

Funder Name
Numico Research B.V. (Netherlands)

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	01/10/2009		Yes	No