Bioequivalence of a diabetes specific tube feed with a new carbohydrate source

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The objective of the study is to assess whether the postprandial glucose response of the adapted product is equivalent to the postprandial glucose response of the original product.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51846

Source
ToetsingOnline

Brief title
EquiDia

Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
niet van toepassing

Health condition

studie met gezonde vrijwilligers

Research involving
Human

Sponsors and support

Primary sponsor: Nutricia Research
Source(s) of monetary or material Support: Nutricia Research BV

Intervention

Keyword: - bioequivalence, - diabetes specific tube feed, - glucose response, - glycemic index

Outcome measures

Primary outcome

Blood glucose iAUC0-120 [mmol/L*min] and the blood glucose iCmax [mmol/L] (test

product versus control product)

Secondary outcome

- GI = blood glucose iAUC0-120 [mmol/L] of test product / mean blood glucose

iAUC0-120 [mmol/L] of reference product

- Glycemic Load (GL) = GI * available carbohydrate/given amount of carbohydrate

Study description

Background summary

Nutricia has a nutritionally complete tube feed specific for diabetes patients on the market. It has been shown that after intake of this product postprandial glucose responses were decreased as compared to standard tube feeds, thereby contributing to achieving glycaemic control, which is one of the major goals in the management of diabetes. The original diabetes specific tube feed requires a change in recipe. This change will be the use of another carbohydrate source and as a consequence there is also a change in the level of carbohydrates. In addition a few minor changes in micronutrient levels will be implemented. These changes in carbohydrate source and amount might impact the postprandial glucose response.

Study objective

The objective of the study is to assess whether the postprandial glucose

response of the adapted product is equivalent to the postprandial glucose response of the original product.

Study design

This is a randomised, single blind, crossover, single-centre study.

Intervention

Test product: diabetes specific tube feed new recipe (approximately 250 ml)
Control product: diabetes specific tube feed original recipe (approximately 250 ml)
Reference product: glucose solution (25 grams of glucose dissolved in 250 ml of water); to determine the glycemic index of the test product

Study burden and risks

Subjects should visit the study site six times: one screening visit, three study visits to measure the glucose response to the reference product and two study visits to measure the glucose response to the test and control product. During each study visit, blood is sampled using a finger prick just before and after the intake at 8 timepoints spread over 2,5 hours for analysis of glucose. A few days after the last study visit a follow-up phone call will be done. During participation subjects should adhere to a number of rules related to medication use and lifestyle. The study will be performed with healthy adult volunteers and the subjects will take a nutritional product or a standard glucose solution once every visit. This is expected to cause minimal discomfort for the subject. The risks of the other study procedure are very limited as well; there is a small risk of experiencing pain/discomfort from finger prick method.
The burden for participants in this study is considered small and the benefits of obtaining more knowledge on the characteristics of nutritional products outweighs the minimal burden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Age >= 18 and <= 65 years
2. Body Mass Index (BMI) >= 18.5 and <= 27.0 kg/m2
3. Written informed consent
4. Willingness and ability to comply with the protocol
5. Judged by the Investigator to be in good health

Exclusion criteria

1. Known Diabetes Mellitus type I or type II, rebound hypoglycaemia and/or any other medical condition that
2. Any use of anticoagulants, systemic steroids, protease inhibitors or antipsychotics and/or any medication known to affect glucose tolerance and/or to influence digestion and absorption of nutrients within 1 week of screening, in opinion of the Investigator
3. Any known disease which influences digestion and absorption of nutrients within 1 week of screening (in the opinion of the Investigator)
4. Allergy to soy and/or any other known relevant food allergy or intolerance in opinion of the Investigator
5. Adherence to a strict vegan diet
6. Adherence to a weight loss program
7. Picky/fussy eater (being very selective about what to eat) or eating disorder
8. Known pregnancy and/or lactation
9. Current smoking or stopped smoking for < 1 month prior to screening (except for incidental smoking of <= 3 cigarettes/cigars/pipes per week on average in

the last month)
10. Average alcohol use of > 21 glasses per week for men or > 14 glasses per week for women (on average during the last 6 months)
11. Drug or medicine abuse in opinion of the Investigator
12. Any known bleeding disorder
13. Active participation in any other clinical study with investigational or marketed products concomitantly or within 4 weeks before study visit 1, in the opinion of the Investigator
14. Major medical or surgical event requiring hospitalization within the preceding 3 months and/or scheduled in the period of study participation relevant in the opinion of the Investigator
15. Investigator*s uncertainty about the willingness or ability of the subject to comply with the protocol requirements
16. Employees of Nutricia Research and/or family members or relatives of employees

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-07-2022
Enrollment:	22
Type:	Actual

Ethics review

Approved WMO

Date:	26-07-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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
CCMO	NL81436.056.22