Glucose response to a formula for patients at risk of hypoglycaemia

Published: 11-01-2023
Last updated: 07-04-2024

The aim of the present study is to assess whether the postprandial glucose response of the new test products is superior to the postprandial glucose response of an original treatment option.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON51388

Source
ToetsingOnline

Brief title
EFFECT

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
not applicable

Research involving
Human

Sponsors and support

Primary sponsor: Nutricia Research
Source(s) of monetary or material Support: Nutricia Research B.V.

Intervention

Keyword: carbohydrate metabolism, glucose response, nutritional product

Outcome measures

Primary outcome

The primary outcome parameter in this study is the rate of decline in glucose (mmol/hour) after reaching peak glucose levels (Cmax) until reaching baseline (t = -5) blood glucose levels or, in case baseline blood glucose levels are not reached, the lowest observed blood glucose level.

Secondary outcome

• incremental Area Under the Curve (iAUC) for:

o glucose (mmol/L/hrs)

o insulin (pmol/L/hrs)

o paracetamol (mg/L/hrs)

• incremental peak levels (iCmax) of:

o glucose (mmol/L)

o insulin (pmol/L)

o paracetamol (mg/L)

• time to peak levels (Tmax) of:

o glucose (min)

o insulin (min)

o paracetamol (min)

Study description

Background summary

Nutricia has a range of formulas on the market including medical formulas addressing specific needs of patients who are at risk for hypoglycaemia. A new product is currently under development.

Study objective

The aim of the present study is to assess whether the postprandial glucose response of the new test products is superior to the postprandial glucose response of an original treatment option.

Study design

The study has a double-blind, crossover design with healthy volunteers taking one serving of the products in a randomized order.

Intervention

Participants will receive a single bolus of study product (50g carbohydrate equivalent) together with paracetamol (1 gram) at the start of each test day.

Study burden and risks

Subjects should visit the study site 4 times: one screening visit and three study visits. During each study visit, the subjects will get a bolus with one of the study products and paracetamol, and blood is sampled using a cannula in the arm at 13 time points in 6 hours for analysis of blood glucose, insulin and paracetamol.
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 3 study products are at random assigned to the subjects on each visit. Participation in the study is expected to cause minimal discomfort for the subject. The risks of the other study procedures are very limited as well; there is a small risk of experiencing pain/discomfort from the cannula. 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

Public
Nutricia Research

Uppsalalaan 12
Utrecht 3584 CT
NL
Scientific
Nutricia Research

Uppsalalaan 12
Utrecht 3584 CT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Healthy individuals, 18 up to and including 50 years of age.
2. Willing to maintain habitual diet, physical activity pattern, and body weight throughout the trial.
3. Willing to avoid the consumption of alcohol, unusual food intake, unusual physical activity 24h prior to each study visit.
4. Willing to come to the study visit in the morning after an overnight fast of minimum 10 hours and maximum 14 hours (with water only).

Exclusion criteria

1. Abnormal blood glucose levels at screening (not fasted) in the opinion of the investigator.

2. Known history of gastrointestinal disease (e.g., diverticulitis, Crohn*s disease, coeliac disease etc.), bariatric surgery, AIDS, hepatitis, a history or presence of clinically important endocrine (including Type 1 or Type 2 diabetes mellitus), or any condition which might, in the opinion of the Principal Investigator either: 1) make participation dangerous to the subject (e.g. anaemia) or to others, or 2) affect the results.
3. Use of medications known to influence carbohydrate metabolism, gastrointestinal function or appetite, including, but not limited to adrenergic blockers, diuretics, thiazolidinediones, metformin and systemic corticosteroids within 4 weeks of the screening visit, or any medication which might, in the opinion of the Principal Investigator either: 1) make participation dangerous to the subject or to others, or 2) affect the results.
4. Use of medications known to influence gastric emptying (including but not limited to anticholinergics, nicotine, narcotic analgesics, ganglion blocking drugs, antacids and metoclopramide).
5. Use of anti-clotting medications.
6. Current tobacco smokers or smokers that quite smoking < 1 month prior to screening (except for occasional (<= 3) cigarettes/cigars/pipes per week on average over the past month).
7. Self-reported pregnancy or breastfeeding.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-02-2023
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	11-01-2023
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	NL82867.056.22