Assessment of the glycemic responses to nutritional products

Published: 04-11-2019
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The objective of this study is to measure the postprandial glycemic response to several nutritional products.

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

Summary

ID

NL-OMON49247

Source
ToetsingOnline

Brief title
GLOW

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
niet van toepassing

Research involving
Human

Sponsors and support

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

Intervention

Keyword: glycemic index, nutritional product

Outcome measures

Primary outcome

GI = Capillary blood glucose iAUC0-120 [mmol/l] of test product/ mean capillary

blood glucose iAUC0-120 [mmol/l] of reference product

Secondary outcome

- GL=GI*available carbohydrate/given amount

- Capillary blood glucose mmol/l and iAUC0-120 [mmol/l*min] of the reference

product and test product(s)

- Capillary blood glucose iCmax [mmol/l] and Tmax [min] of the reference

product and test product(s)

- Appetite profile and liking of the test product using visual analogue scales

Study description

Background summary

Elevated blood glucose levels (hyperglycemia) are known to cause metabolic changes that affect health and disease parameters. Several studies indicate that improvement in glycemic control results in lower rates of hospital complications.
The GI is an intrinsic property of a food that reflects the postprandial glycemic impact compared with an equivalent carbohydrate portion of glucose in solution. Low GI foods are those containing carbohydrates causing less fluctuation in blood glucose and insulin levels than high GI foods.
To our knowledge, the GI of the study products have not been measured. The aim of this study is therefore to measure the postprandial glycemic response to these products.

Study objective

The objective of this study is to measure the postprandial glycemic response to several nutritional products.

Study design

This is a randomised controlled, open label, single-centre study.

Intervention

- Several nutritional products containing 25 or 50 grams of carbohydrates (testproduct)
- Standard glucose solution (reference product) (250 ml, contains 25 or 50 grams of glucose)

Study burden and risks

Subjects should take during the study visits (with a minimum of 48 hours between the separate visits) a nutritional product containing 25 or 50 grams carbohydrates or a standard glucose solution (250 ml, contains 25 or 50 grams of glucose). During a 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 and a questionnaire is completed at 4 timepoints. 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. The intake of the nutritional products is not expected to cause adverse events. The intake of the standard glucose solution may cause nausea, stomach complaints and/or thirst. The risks of the other study procedure are very limited as well and will be performed / guided by qualified study staff.
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)
Elderly (65 years and older)

Inclusion criteria

1. Age * 18 and * 60 years
2. Body Mass Index (BMI) * 18.5 and * 24.9 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 hypoglycemia and/or any other medical condition that interferes with glucose metabolism
2. Any use of anticoagulants, 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 influence digestion and absorption of nutrients within 1 week of screening
4. Any known food allergy or intolerance
5. Adherence to a strict vegan diet and/or a weight loss program
6. Any known bleeding disorder

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-11-2019
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	04-11-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-02-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	17-07-2020
Application type:	Amendment
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

ID: 22371
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL71190.056.19
Other	NTR: NL8151