The effect of arabinose on sucrose-induced glycemic response and glycemic kinetics as measured by a dual stable isotope methodology

Published: 08-08-2018
Last updated: 19-03-2025

To compare the digestion and absorption kinetics following the ingestion of sucrose plus arabinose versus sucrose only in healthy, young subjects.

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

Summary

ID

NL-OMON45763

Source
ToetsingOnline

Brief title
Sucrose + Arabinose

Condition

- Other condition

Synonym
high blood glucose, Hyperglycemia

Health condition

This study will evaluate the glycemic response to sucrose with the addition of L-arabinose

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Sensus B.V.

Intervention

Keyword: Food supplements, Hyperglycemia, Nutrition

Outcome measures

Primary outcome

Total rate of glucose appearance (RaT), exogenous rate of glucose appearance (RaE), total rate of glucose disappearance (RdT) and exogenous rate of glucose disappearance (RdE) from percentage of [6,6-2H2]-glucose and of ingested 13C-glucose from sucrose-(glucose-13C6) in plasma glucose; plasma glucose and insulin concentrations.

Secondary outcome

Plasma FFA and glycerol, whole-body carbohydrate and fat oxidation rates using indirect calorimetry.

Study description

Background summary

A good glycemic control is essential for cardiometabolic health. Hyperglycemia and glycemic variability have been indirectly or causally related to obesity, T2DM and cardiovascular disease. A delay in and/or inhibition of carbohydrate digestion may assist in avoiding hyperglycemia and may therefore be useful in the prevention of chronic metabolic diseases. L-arabinose may act as a sucrose substitute in many foods and may have beneficial effects due to its uncompetitive inhibition of sucrase activity, which then inhibits sucrose digestion. This project will compare the glycemic and insulinemic responses as well as the glycemic kinetics of a sucrose plus arabinose load vs. a sucrose only load.

The purpose of the present experiment is to compare the glycemic and insulinemic responses as well as the glycemic kinetics of a sucrose load with and without the addition of arabinose. Several studies have shown that differences in the glycemic index may not only reflect the differences in the exogenous rate of appearance (RaE), but also differences in endogenous rate of appearance (hepatic glucose production, EGP), and in peripheral glucose disposal (Rd). To compare plasma glucose kinetics after sucrose or sucrose/arabinose, we will use a dual stable isotope methodology with sucrose-(glucose-13C6), added to a sucrose(/arabinose) drink, and intravenous infusion of [6,6-2H2]-glucose.

Study objective

To compare the digestion and absorption kinetics following the ingestion of sucrose plus arabinose versus sucrose only in healthy, young subjects.

Study design

Double-blinded, randomized crossover study.

Intervention

We will assess the glycemic and insulinemic responses and glycemic kinetics after the ingestion of a beverage containing sucrose plus arabinose and compare those to the ingestion of a beverage containing sucrose only. This is done in a randomized, crossover manner. There will be a two-week washout period between the two beverages.

Study burden and risks

The burden and risks involved in participating in this experiment are small. Insertion of the catheters in a vein is comparable to a normal blood draw and the only risk is a small local hematoma. During one visit for the experimental trial, 12 blood samples (± 120 ml total) will be obtained. The total amount of blood collected is much less than the amount of a normal blood donation (500 ml) and will be completely restored in several weeks. The [6,6-2H2]-glucose tracer that will be infused intravenously during the experimental trial is produced according to GMP standards and is safe for human use. Arabinose is currently used as a supplement or flavor ingredient in Europe. The arabinose and sucrose-(glucose-13C6) are also produced according to safety standards. Participants will visit the university three times after an overnight fast, either by public transport or by having someone drive them. The first visit will involve a screening and will last the whole morning, during which the eligibility of the participant will be assessed. We will ask the participants to fill out a medical questionnaire and we will perform a DEXA scan and a 2 h OGTT. For the second and third visit, during which the experimental trial will

take place, participants are required to come to the university in a fasted state, not having consumed any food or beverages except for water as from 22:00 the evening before. Also, 3 days prior to the experimental trial participants need to record their food intake and activities performed. During these 3 days participants are not allowed to perform heavy physical exercise or drink alcohol.
There is no direct benefit for the participants, except from their contribution to scientific knowledge and the development of novel concepts to prevent hyperglycemia.

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

- Male/Female

- Aged 18-35 y
- BMI 18.5 - 25.0 kg/m2
- Healthy
- Recreationally active (participating in recreational sports activities <= 3 times per week)

Exclusion criteria

- Smoking
- Food allergies
- Diagnosed diabetes (type 1 or type 2); fasting glucose >=7.0 mmol/l and/or glucose >=11.1 mmol/l after 2 h OGTT
- Diagnosed metabolic or gastrointestinal disorders
- Previous participation in a 13C-glucose or 2H-glucose tracer study within the last two weeks
- Unstable weight over the last three months
- Blood donation in the past two months
- Use of medication
- High alcohol consumption (>2 drinks per day; >7 drinks per week)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-10-2018
Enrollment:	13
Type:	Actual

Ethics review

Approved WMO Date:	08-08-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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: 24860
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL65825.068.18
OMON	NL-OMON24860