The effect of arabinose on sucrose hydrolysis by sucrase and glucose absorption and glycaemic response

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

Summary

ID

NL-OMON42017

Source
ToetsingOnline

Brief title
Ara-study

Condition

- Other condition

Synonym
diabetes, metabolic diseases

Health condition

obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Cosun Biobased Products
Source(s) of monetary or material Support: Cosun Biobased Products B.V.

Intervention

Keyword: ad libitum energy intake, arabinose, glucose, insulin

Outcome measures

Primary outcome

The glycaemic response, measured as AUC of plasma glucose during 180 minutes.

Secondary outcome

1) The insulin response, measured as AUC of plasma insulin during 180 minutes.

2) The recovery of stable isotope in breath as a marker for sucrose

metabolisation during 180 minutes.

3) Ad libitum energy intake, measured as lunch after 240 minutes.

4) Appetite, measured using a VAS-questionnaire during 300 minutes.

5) Gastro-intestinal comfort using a questionnaire.

6) Study diary.

Study description

Background summary

One compound that is currently of interest is arabinose. Arabinose is a slowly absorbed pentose with a sweet taste, which is naturally present in plants. It can be derived from plant materials, such as sugar beets, by enzymatic hydrolysis. Arabinose can act as a sucrose substitute in many foods, among which fruit-based drinks and muffins.

Study objective

The primary objective is to quantify and compare the effect of added arabinose

to sucrose containing liquid and solid food products on glycaemic response and sucrose hydrolysis by sucrase and glucose absorption in healthy humans.

The secundary objectives are:
1) To compare the effects of arabinose with xylose on glycaemic response and sucrose hydrolysis by sucrase and glucose absorption in a sucrose containing liquid food product.
2) To determine the effect of arabinose in liquid and solid sucrose containing food products on ad libitum energy intake in a secondary meal.
3) To compare the effect of arabinose with xylose in liquid sucrose containing food products on ad libitum energy intake in a secondary meal.
4) To determine the effect of arabinose in liquid and solid sucrose containing food products on appetite feelings.
5) To compare the effect of arabinose with xylose in liquid sucrose containing food products on appetite feelings.
6) To determine the acceptability of the treatments as measured by gastro-intestinal comfort.

Study design

A randomized cross-over trial with 5 treatments, including a within subjects design. There will be a washout period between treatments of one week. The treatments are 1) Control drink; 2) Xylose drink; 3) Arabinose drink; 4) Control muffin; and 5) Arabinose muffin. The drinks will be randomly offered in the first three weeks and the solids will be offered randomly in the last two weeks. Plasma glucose and insulin, 13C in exhaled breath, appetite and gastro-intestinal comfort will be measured.

Intervention

All subjects will receive five interventions in an order randomized within drinks and muffins. The food products will be consumed in fasting state as a breakfast 1) Control drink, a fruit-based drink; 2) Xylose drink, a fruit-based drink with added xylose (xylose added as 10 wt% of sugar); 3) Arabinose drink, a fruit-based drink with added arabinose (arabinose added as 10 wt% of sugar); 4) Control muffin; 5) Arabinose muffin, a muffin with added arabinose (arabinose added as 10 wt% of sugar).

Study burden and risks

The intervention is non-therapeutic to the subject. The risk associated with participation is negligible and the burden can be considered as moderate. Xylose and arabinose are pentoses. Xylose, arabinose and 13C are present in a wide range of plants, and form a part of the daily diet of most of the world*s population. Xylose and arabinose used in this experiment are extracted from sugar beets. The safety of xylose and arabinose is not yet evaluated by legal

authorities and it has not yet been classified as GRAS in the USA and as novel food ingredient in the EU. However, in Japan and the USA these compounds are used in foods. Also in Europe research has been done to these compounds in humans. All treatments include a stable isotope tracer for sucrose absorption. After signing the informed consent the following measurements and questionnaires will be taken: General questionnaire, health questionnaire and Dutch Eating Behaviour Questionnaire. At screening the following measurements will be taken: height, body weight, fasting blood via finger prick to determine glucose and Hb concentration. Before the experimental test days, subjects will get an evening meal before the test day distributed by the study team. During the test day subjects need to come in a fasting state to the University. Then, 8 blood samples (in total 56 ml) and 9 breath bags will be collected in 180 minutes. Also ad libitum energy intake will be measured at lunch at 240 minutes after baseline. As well as a gastro-intestinal comfort questionnaire, an appetite questionnaire and an evaluation questionnaire to ask which treatment they thought they had. The total study lasts for five weeks. So, including the information meeting and screening the subjects need to visit the University seven times.

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
• 18-35 Years old while signing the informed consent
• Good Dutch speaking, writing, understanding
• Healthy: as judged by the subject
• BMI: 18.5-25 kg/m2
• Stable body weight, i.e. no reported weight loss or weight gain of > 5 kg in the two months prior to the screening session
• Normal fasting glucose concentration <6.1 mmol/L
• Normal Hb concentration >8.5 mmol/L

Exclusion criteria

• Allergy, intolerance or oversensitivity for the food products under study
• Having a history of medical or surgical events that may affect the study outcome
• Having reported gastro-intestinal problems
• Medical drug use that may affect the study outcome
• Current antibiotics usage or in the two months prior to the screening session
• Not willing to eat muffins or to drink fruit-based drinks
• Being a vegetarian (not willing to eat meat)
• Use of dietary supplements that may affect the study outcome
• Currently using a slimming or medically prescribed diet or having used one in the two months prior to the screening session
• Excessive alcohol consumption (>21 glasses/week on average)
• Mental status that is incompatible with the proper conduct of the study
• Elite athletes, i.e. exercise > 7h/week vigorously
• Planning to change physical activity pattern during the study period
• Having blood vessels that are too difficult for inserting a cannula, as judged by the study nurse
• Recent blood donation (<1 month prior to Day 01 of the study)
• Willing to donate blood during the study
• Not having a general practitioner
• Being an employee of Wageningen University, department of Human Nutrition
• Current participation in other research

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):	12-05-2015
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO

Date:	07-04-2015
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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: 23134
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL51738.081.15
OMON	NL-OMON23134