The effect of L-arabinose on the glycaemic and insulinemic response after consumption of a liquid product.

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The objective of the study is to determine and compare the effects of L-arabinose added to 1) water with sucrose, 2) water with sucrose and fat, and 3) water with sucrose and starch on glycaemic and insulinemic responses in healthy adults. The...

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

Summary

ID

NL-OMON45701

Source
ToetsingOnline

Brief title
Ara3-study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes type 2, metabolic diseases

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Bio-Based Industries Joing Undertaking; Bio-Based Industries Consortium; Horizon 2020 European Funding for Research&Innovation

(H2020-BBI-PPP-2014-1) under Grant Agreement number 669105 (PULP2VALUE)

Intervention

Keyword: glucose, insulin, L-arabinose

Outcome measures

Primary outcome

The primary outcomes are glycaemic and insulinemic response.

Secondary outcome

Secondary outcomes are:

1) appetite ratings,

2) subsequent ad libitum energy intake,

3) tolerance of the treatments,

4) gastro-entero endocrine markers,

5) L-arabinose in the blood, and

6) excretion of L-arabinose in urine.

Study description

Background summary

L-arabinose is a pentose which is naturally present in plants, e.g. in the sugar beet. L-arabinose is a sucrase inhibitor and lowers glucose and insulin responses when it is consumed together with sucrose. However, when L-arabinose is consumed in a muffin, in cereal clusters or in a mixed meal, no significant lowering of the glycaemic response was observed. Fat, starch and protein are nutrients present in solid products and less in drinks. We hypothesize that the macronutrient content of the meal disturbs the positive effect of L-arabinose. We expect that fat will reduce the glycaemic response by delaying gastric emptying, which causes a slower entrance in the duodenum of sucrose and L-arabinose. For starch we expect that the glycaemic response will be so much increased that the inhibiting effect on sucrase may be diminished, by an increased presence of glucose in the duodenum. For now, we want to know how

much the separate effects of fat and starch will be.

Study objective

The objective of the study is to determine and compare the effects of L-arabinose added to 1) water with sucrose, 2) water with sucrose and fat, and 3) water with sucrose and starch on glycaemic and insulinemic responses in healthy adults.

The secondary aims are to determine and compare the effects of L-arabinose added to 1) water with sucrose, 2) water with sucrose and fat, and 3) water with sucrose and starch on:
1) appetite ratings,
2) subsequent ad libitum energy intake,
3) tolerance of the treatments,
4) gastro-entero endocrine markers,
5) L-arabinose in the blood, and
6) excretion of L-arabinose in urine.

Study design

The study is a randomized cross-over trial with six treatments divided in three blocks and blind within the blocks. All participants will receive 6 treatments in a randomized order. There will be a washout period between treatments of a minimum of three days. The test products will be consumed after an overnight fast.

Intervention

All products contain 50g sucrose and 250g water. The testproducts are:
1) Control sucrose solution (50g sucrose)
2) L-arabinose sucrose solution (Control + 5g L-arabinose)
3) Sucrose and fat solution (Control + 22g fat)
4) Fat L-arabinose and sucrose solution (Control + 5g L-arabinose + 22g fat)
5) Sucrose and starch solution (Control + 50g starch)
6) Starch L-arabinose and sucrose solution (Control + 5g L-arabinose + 50g starch)

Study burden and risks

The intervention is non-therapeutic to the subjects. The risk associated with participation is negligible and the burden can be considered as moderate. L-arabinose is a pentose which is present in a wide range of plants, such as sugar beet. The safety of L-arabinose is evaluated by legal authorities and it has been classified as self-affirmed GRAS in the USA.
After signing the informed consent the following measurements and

questionnaires are 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. On the evenings before the experimental test days, subjects will consume every time the same evening meal. During the test morning subjects need to come in a fasting state to the University. Then, 8 blood samples (80 ml per test morning) and appetite questionnaires will be collected in 180 minutes, subsequent ad libitum lunch intake, as well as a gastro-intestinal comfort questionnaire, and an evaluation questionnaire to ask which treatment they thought they had. Additionally, subjects will collect urine for 24h during and after the test day. The total study lasts for six weeks. So, including the information meeting, screening and returning their urine containers the subjects need to visit the University 14 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

- 18-35 years old while signing the informed consent
- good Dutch writing, speaking, understanding
- healthy: as judged by the participant
- stable body weight, i.e. no reported weight loss or weight gain of >5kg in the two months prior to the screening session
- normal Fasting glucose concentration <6.1mmol/L, measured by finger prick
- normal hemoglobine (Hb) concentration >8.5 mmol/L for men and >7.5 mmol/L for females, measured by finger prick

Exclusion criteria

- women being pregnant or lactating
- allergy, intolerance or oversensitivity for food products
- having a history of medical or surgical events that may affect the study outcome
- having 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 or drink the test products
- 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)
- 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 the first testday of the study)
- planning to donate blood as a blood donor during the study
- not having a general practitioner
- being an employee or student performing their thesis or internship of Wageningen University, division of Human Nutrition
- current participation in other research

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-08-2017
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	29-06-2017
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: 22940
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL61428.081.17
OMON	NL-OMON22940