The effect of L-arabinose on glycaemic and insulinemic response in a liquid and a solid product.

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The main objective is to determine and compare the effect of partly substituting sucrose by L-arabinose in a sucrose solution and in a cereal cluster on glycaemic responses and insulinemic responses in healthy humans. Secondary objectives are: To...

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

Summary

ID

NL-OMON43485

Source
ToetsingOnline

Brief title
Ara2-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 Joint 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

1) Glycaemic response, measured as iAUC, peak and time-to-peak of blood glucose

during 180 minutes;

2) Insulinemic response, measured as AUC, peak and time-to-peak of plasma

insulin during 180 minutes;

Secondary outcome

3) L-arabinose in plasma;

4) GLP-1 in plasma;

5) Subsequent ad libitum food intake, measured as total energy and

macronutrient intake;

6) Appetite feelings, measured by a VAS-questionnaire at multiple time points

during 180 minutes;

7) Gastro-intestinal comfort using a questionnaire;

8) Study diary;

9) L-arabinose in urine.

Study description

Background summary

L-arabinose is a pentose which is naturally present in plants. L-arabinose can act as a sugar substitute in many foods, among which drinks and cereal

clusters.

Study objective

The main objective is to determine and compare the effect of partly substituting sucrose by L-arabinose in a sucrose solution and in a cereal cluster on glycaemic responses and insulinemic responses in healthy humans.

Secondary objectives are:
To determine and compare the effect of partly substituting sucrose by L-arabinose in a sucrose solution and in a cereal cluster on:
1) the absorption and excretion of L-arabinose.
2) plasma GLP-1 concentration.
3) subsequent ad libitum energy intake.
4) appetite feelings.
5) the acceptability of the treatments as measured by gastro-intestinal comfort.

Study design

The study is a randomized within blocks, cross-over study. The liquids treatment is open labelled, for the cereal clusters the study is double-blind. All subjects will receive six interventions in an order randomized within solutions and cereal clusters. The food products will be consumed in fasting state as a breakfast. All control products contain 50g available carbohydrates. In the drinks, one treatment 30% (i.e. 15g) of the sucrose will be replaced by L-arabinose, the other treatment 15g L-arabinose without sucrose will be added to water; in the cereal clusters 10% and 15% sucrose will be replaced by L-arabinose.

Intervention

The food products will be consumed in fasting state as a breakfast. All control products contain 50g available carbohydrates. In the drinks, one treatment 30% (i.e. 15g) of the sucrose will be replaced by L-arabinose, the other treatment 15g L-arabinose without sucrose will be added to water; in the cereal clusters 10% and 15% sucrose will be replaced by L-arabinose.

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. L-arabinose is a pentose. L-arabinose is present in a wide range of plants, and form a part of the daily diet of most of the world*s population. The safety of L-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.
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. On the evenings before the experimental test days, subjects will consume an evening meal distributed by the study team. During the test day subjects need to come in a fasting state to the University. Then, 8 blood samples via a catheter 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. The total study lasts for six weeks. So, including the information meeting, screening and returning urine the subjects need to visit the University fourteen 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 speaking, writing, understanding
• Healthy: as judged by the subject
• 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, 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 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 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 Day 1 of the study)
• Planning to donate blood as a blood donor during the study
• Not having a general practitioner
• Being an employee or a student doing a thesis or internship at the 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):	23-05-2016
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO

Date:	05-04-2016
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

No registrations found.

In other registers

Register	ID
CCMO	NL55974.081.15