The effect of L-arabinose on glycaemic responses in subjects at risk of developing type II diabetes

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To examine whether L-arabinose addition to a sucrose drink will lower glycaemic and insulinemic responses in people at increased risk of developing type II diabetes.

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

Summary

ID

NL-OMON45845

Source
ToetsingOnline

Brief title
Ara4-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 Joined Undertaking; Bio-Based Industries Consortium; Horizon 2020 European Funding for Research&Innovation (H2020-BBI-PPP-2014-1) under Grant Agreement 669105 (Pulp2Value)

Intervention

Keyword: glucose, insulin, L-arabinose

Outcome measures

Primary outcome

Glycaemic response

Secondary outcome

Insulin response, glucagon response, satiety response, glucose monitoring,

gastro-intestinal tolerance

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. Almost all research that was done with arabinose consumption has been done in young healthy subjects and were done in an acute setting.

Study objective

To examine whether L-arabinose addition to a sucrose drink will lower glycaemic and insulinemic responses in people at increased risk of developing type II diabetes.

Study design

The study is a randomized, cross-over study. All subjects receive 2 different products in a randomized order. There will be a washout of 5 days. The test products will be consumed in the morning when subjects are fasting. Thereafter they will receive 2 days of controlled nutrition.

Intervention

Addition of 10% arabinose to a sucrose drink.
And we will explore the addition of 15% of arabinose to a normal diet.

Study burden and risks

After signing the informed consent the following measurements and questionnaires will be taken: General questionnaire, health questionnaire, and diabetes risk score questionnaire. At screening the following measurements will be taken: height, body weight, waist and hip circumference, food frequency questionnaire, fasting, 1h and 2h blood via finger prick after OGTT to determine glucose response, and Hb concentration. On the evenings before the experimental test days, subjects will consume every time a standardized evening meal. During the test days subjects need to come in a fasting state to the University and need to eat the controlled diet with or without L-arabinose supplementation. Then, 8 blood samples (80 ml per test morning) and appetite questionnaires will be collected in 180 minutes, as well as a gastro-intestinal comfort questionnaire. Including the information meeting, and the screening, the subjects need to visit the University 7 times.
During this 2-week period the following measurements will be taken: body weight (1x), blood samples (16x), glucose monitoring (14 days), wellbeing diary (14 days).

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.

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

* Age between 55-80 years
* BMI * 25.0 kg/m2
* Impaired fasting glucose (IFG; fasting glucose * 5.6 and < 7.0 mmol/L) or
* HbA1C: * 39 < 49 mmol/mol

Exclusion criteria

* Diagnosed diabetes,
* Diagnosed liver, pancreas or endocrine diseases which could affect the study results,
* Having gastro-intestinal problems,
* Use of medication or supplements which could affect the study results (Moreover, chronic medication and supplements should be used as normal when they donot affect the study results),
* Allergy, intolerance or oversensitivity for food products,
* Sensitive to medical skin adhesives,
* Following a medically prescribed, low energy or low carbohydrate diet,
* Unwilling to consume the provided diets,
* >5 kg weight change during the last 3 months,
* Current antibiotics usage or in the two months prior to the screening session,
* Excessive alcohol consumption (>21 glasses/week on average for men and >14 glasses/week for women),
* Having blood vessels that are too difficult for inserting a cannula, as judged by the study nurse,
* Not normal haemoglobin (Hb) concentration: <8.5 mmol/L for men and <7.5 mmol/L for women,
* Recent blood donation (<1 month prior to the first study day),
* Planning to donate blood as a blood donor during the study,
* Mental status that is incompatible with the conduct of the study,
* Being an employee of Wageningen University, division of Human Nutrition and Health,
* Current participation in other research (except EetMeetWeet).

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):	16-11-2018
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO

Date:	16-10-2018
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: 27001
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL66558.081.18
OMON	NL-OMON27001