The effect of arabinose on glycaemic responses in subjects at risk of developing type 2 diabetes.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27001

Source
Nationaal Trial Register

Brief title
Ara4-studie

Health condition

Glucosemetabolisme, metabole gezondheid

Sponsors and support

Primary sponsor: Wageningen University (WUR)
Source(s) of monetary or material Support: EU grant

Intervention

Outcome measures

Primary outcome

blood glucose and insulin levels

Secondary outcome

continuous glucose during 48 h, appetite ratings, side effects

Study description

Background summary

L-arabinose is a pentose which is naturally present in plants. L-arabinose is a sucrase inhibitor and thereby lowers glycaemic and insulinemic responses when consumed together with sucrose as a drink in young healthy subjects. Still, we don’t know if this effect is also observed in subjects that are less able to regulate their glucose levels. Further, long term effects such as 24h or 48h glucose responses are scarce.The main objective is to determine the effect of drinking a solution of sucrose with arabinose on glycemic responses in prediabetic subjects. Secondary objectives are continuous glucose responses, appetite ratings, tolerance of the treatments, L-arabinose in the blood, and excretion of L-arabinose in urine. The study is a randomized double-blind cross-over study with a washout period of 5 days. Eighteen subjects between 55-80y old with increased risk of developing type II diabetes will be included. The drinks will be consumed in fasting state as a breakfast. Further, lemonades with or without arabinose will be provided to drink before every meal during 48h, when meanwhile continuous blood glucose is measured.

Study objective

Addition of arabinose lowers glycemic repsonses in subjects at risk of developing type 2 diabetes

Study design

Every subject will visit University 5 times, an information meeting, a screening including a fasting glucose, Hb and HbA1c, 2 test days and removal of the glucose sensor.

Plasma collection: 0, 15, 30, 45, 60, 90, 120, 180 minutes.

Intervention

Sugar drink with and without arabinose. And arabinose supplementation during 2 days

Contacts

Public
Wageningen UR, Afdeling Humane Voeding, Bode 62

Korrie Pol
Postbus 8129

Wageningen 6700 EV
The Netherlands
Scientific
Wageningen UR, Afdeling Humane Voeding, Bode 62

Korrie Pol
Postbus 8129

Wageningen 6700 EV
The Netherlands

Eligibility criteria

Inclusion criteria

- Age range of ≥ 55 and < 80 years old,

- BMI ≥ 25 <40 kg/m2,

- Impaired fasting glucose (IFG; fasting glucose ≥ 5.6 and < 7.0 mmol/L) or

- HbA1C: ≥ 39 < 49 mmol/mol

Exclusion criteria

- Diagnosed with diabetes,

- Having other diseases, including amongst others liver, pancreas and endocrine diseases, which could affect the study results.

- Having gastro-intestinal problems,

- Use of medications or supplements that could influence the study results (chronic medications or supplements should be used as normal),

- 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,

- More than 5kg weight change in the last 3 months,

- Current antibiotics usage or in the two months prior to the first test day,

- Excessive alcohol consumption (>21 glasses/week for men and >14 glasses/week for women on average),

- 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,

- Mentally incompetent or not being able to perform the measurements according to the protocol,

- Not having a general practitioner,

- 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
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-11-2018
Enrollment:	18
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-10-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45845
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6761
NTR-old	NTR7630
CCMO	NL66558.081.18
OMON	NL-OMON45845

Study results