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

No registrations found.

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

Summary

ID

NL-OMON22940

Source Nationaal Trial Register

Brief title Ara3-study

Health condition

Eating behaviour, Obesity, Diabetes Mellitus, Metabolic health

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 insuline levels

Secondary outcome

appetite ratings, ad libitum energy intake, remainder of the day intake, tolerance of the treatments, gastro-entero endocrine markers, L-arabinose levels, excretion of L-arabinose

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. However, when L-arabinose is consumed in solid form or in a mixed meal, no glycaemic lowering was observed. The main objective is to determine the disturbing effects of the macornutrients fat and starch, which are more often found in solid food products, on the reducing glycemic and insulinemic responses of L-arabinose after ingestion of a combined L-arabinose-sucrose drink with or without these macronutrients. Secondary objectives are appetite ratings, subsequent ad libitum energy intake, tolerance of the treatments, gastro-entero endocrine markers, L-arabinose in the blood, and excretion of Larabinose in urine.

The study is a randomized within blocks, cross-over study. Within the three blocks sucrose, starch and fat, the study is double-blind.

All subjects will receive six interventions in a randomized order. Twentyfour healthy adults between 18-35y old will be included. The food products will be consumed in fasting state as a breakfast. All products contain 50g available carbohydrates.

Study objective

The main objective is to understand the effects of the addition of L-arabinose to a drink that has disturbing factors like fat and starch on the reducing glycemic and insulinemic responses of L-arabinose after ingestion of a combined L-arabinose-sucrose drink with or without these macronutrients.

Study design

Every subject will visit the research site 8 times:

- 1: For an information meeting;
- 2: For a screening meeting;
- 3: 6 test sessions

A. Blood collection and appetite feelings by VAS questionnaire: baseline, 15, 30, 45, 60, 90, 120, 180 minutes after start of the treatment;

- B. Ad libitum test meal at 190 minutes after start of the treatment;
- C. Gastro-intestinal comfort at baseline and 3 hours after start of the treatment.

Intervention

1) Sugar drink; 2) L-arabinose and Sugar drink; 3) Sugar and Starch drink; 4) L-arabinose and Sugar and Starch drink; 5) Sugar and Fats drink; 6) L-arabinose and Sugar and Fat drink

Contacts

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Eligibility criteria

Inclusion criteria

- 18-35 years old while signing the informed consent
- · Good Dutch speaking, writing, understanding
- Healthy: as judged by the subject
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• 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 <6.1 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 gastro-intestinal problems

• Medical drug use prescribed by a physician (except contraceptives, antihistamines, and occasionally painkillers)

- Use of dietary supplements 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 (\geq 21 glass/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 study day)
- Planning to donate blood as a blood donor during the study
- Not having a general practitioner

• Being an employee or student doing a thesis or internship of Wageningen University, division of Human Nutrition

• Current participation in other research

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):	18-09-2017
Enrollment:	24
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	04-08-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45701 Bron: ToetsingOnline Titel:

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

No registrations found.

In other registers

ID
NL6458
NTR6636
NL61428.081.17
NL-OMON45701

Study results