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

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27001

Bron
Nationaal Trial Register

Verkorte titel
Ara4-studie

Aandoening

Glucosemetabolisme, metabole gezondheid

Ondersteuning

Primaire sponsor: Wageningen University (WUR)
Overige ondersteuning: EU grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

blood glucose and insulin levels

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	16-11-2018
Aantal proefpersonen:	18
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-10-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45845
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten