In vivo evaluation of high-amylose potato products using the dual isotope technique in healthy men.

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Consumption of potato products with a higher amylose/amylopectin ratio is expected to result in increased colonic fermentation as well as in lower postprandial glucose and insulin concentrations compared to the consumption of conventional potato...

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

Samenvatting

ID

NL-OMON25464

Bron
Nationaal Trial Register

Verkorte titel
HAM-study

Aandoening

Insulin resistance, Type 2 diabetes mellitus

Ondersteuning

Primaire sponsor: Projectgroep WP 11 of the Carbohydrate Competence Center (CCC) consisting of
•TNO Quality of Life, Zeist, NL
•HZPC Holland BV, Metslawier, NL
•Cosun Food Technology Centre, Roosendaal, NL
•University Medical Center Groningen, Groningen, NL

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Overige ondersteuning: Carbohydrate Competence Centre (CCC), Paterswoldseweg 810, 9728 BM Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main parameters of this study are the rate of appearance of exogenous glucose in plasma (glucose kinetics) as well as the quantity of fermentation products.
Glucose kinetics is calculated using total plasma glucose concentration, the 13C/12C-ratio of glucose in plasma samples, and the 2H/1H-glucose ratio in plasma samples.
Parameters of fermentation measured are hydrogen in breath, 13CO2 in breath, short chain fatty acids in plasma and urine.

Toelichting onderzoek

Achtergrond van het onderzoek

Consumption of potato products with a higher amylose/amylopectin ratio is expected to result in increased colonic fermentation as well as in lower postprandial glucose and insulin concentrations compared to the consumption of conventional potato products. This will be investigated in young, healthy men using the dual isotope technique.

Doel van het onderzoek

Consumption of potato products with a higher amylose/amylopectin ratio is expected to result in increased colonic fermentation as well as in lower postprandial glucose and insulin concentrations compared to the consumption of conventional potato products.
A lower glycemic response is favourable for patients with Type 2 Diabetes Mellitus (T2DM) and might also decrease the risk of developing obesity and T2DM.

Primary Objective:

To investigate the differences in rate and extent of digestion as well as in colonic fermentation of HAM compared to that of CON (using the dual isotope technique).

Secondary Objectives:

To investigate what is the difference in glycemic and insulinemic response and the plasma concentrations of incretins and inflammation markers after consumption of HAM compared to CON.

Onderzoeksopzet

Blood samples are drawn during the whole 15h study period (2x) via a venous catheter and several breath and urine samples will be collected.

Onderzoeksproduct en/of interventie

In this explorative intervention study two different test meals will be consumed, with at least one week between each test meal. In the test meals, which will be made from potato puree and starch, the ratio of amylose and amylopectin will differ. The high amylose test meal will have an amylose/amylopectin ratio of 50/50, whereas the conventional test meal will have an amylose/amylopectin ratio of 20/80 (which is the ratio in potatoes).

The volunteer will drink 250 mL of water with the test meal. The test meals are enriched with the stable isotope 13C and volunteers are infused with a tracer amount of the stable isotope 2H for 6 h. This method called the ¡®dual isotope technique¡¯ is used in order to calculate glucose kinetics.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy male volunteer aged ≥ 18;

2. Used to eat breakfast (solid food);

3. Not involved in intensive sportive activities more than twice a week (e.g. playing football, tennis, running, race-cycling, swimming);

4. Produces hydrogen after ingestion of fermentable carbohydrates;

5. Stable weight and no intention to loose weight until completion of the study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Diabetes mellitus;

2. Gastrointestinal disorders (including constipation);

3. BMI < 18 or > 25 kg/m2;

4. Not being able to fast overnight (12 hours);

5. Intake of medication (from 2 weeks before screening until the end of the study, except for sporadic use of paracetamol and/or treating an AE);

6. Undergone digestive tract surgery (except appendectomy);

7. Intake of antibiotics in the three months before the study;

8. Intake of pre- or probiotics more than once per week;

9. Donation of blood (> 500 mL) within the last 3 months prior to admission to the clinic;

10. Inflammatory disease (possibly interfering with measurement of parameters in this study);

11. Participation to another clinical study within 90 days before enrolment;

12. Positive drug screen or alcohol breath test at day before study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	06-09-2010
Aantal proefpersonen:	12
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	12-11-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35079

Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2491
NTR-old	NTR2608
CCMO	NL31397.056.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35079

Resultaten

Samenvatting resultaten
N/A