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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25464

Source
Nationaal Trial Register

Brief title
HAM-study

Health condition

Insulin resistance, Type 2 diabetes mellitus

Sponsors and support

Primary 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

Project leader:
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Source(s) of monetary or material Support: Carbohydrate Competence Centre (CCC), Paterswoldseweg 810, 9728 BM Groningen

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

The secondary study parameters are plasma concentrations of total blood glucose, insulin, incretins and markers of inflammation. Sensation of appetite and satiety (VAS registration) as well as feeling and extent of discomfort after consumption of the test meal are also considered as secondary parameters. Other study parameters include body weight, BMI, family history of T2DM, habitual diet, smoking habits and sportive activities.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-09-2010
Enrollment:	12
Type:	Actual

Ethics review

Positive opinion

Date:	12-11-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35079
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
N/A