The effect of the consumption of different wheat products on glucose kinetics and metabolic effects in healthy men - Part 2.

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

Samenvatting

ID

NL-OMON21832

Bron
NTR

Verkorte titel
TIFN2

Aandoening

EN: Insulin resistance/Type 2 diabetes mellitus
NL: Insuline resistentie/Type 2 diabetes mellitus

Ondersteuning

Primaire sponsor: Top Institute Food and Nutrition (TIFN)
Overige ondersteuning: Top Institute Food and Nutrition (TIFN)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main parameters of this study are postprandial plasma concentrations of glucose and insulin as well as the rate of appearance of exogenous glucose in plasma (glucose kinetics). 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.

Toelichting onderzoek

Achtergrond van het onderzoek

Wheat products differ in their glycemic and insulinemic response, which is influenced by the processing of the product. Underlying mechanisms will be investigated in young, healthy men (from The Netherlands) consuming four differently processed wheat products (using the dual isotope technique).

Doel van het onderzoek

Consumption of slowly digestible starch is implicated with a decreased risk for the development of obesity, insulin resistance and Type 2 diabetes (T2DM). Underlying mechanisms of this beneficial effect are not yet elucidated. The objective of this study is to investigate the differences in glucose kinetics (dual isotope technique) and metabolic response (glucose, insulin, incretins) of four differently processed wheat products which are expected to differ in their rate of starch digestion and their glycemic and insulinemic response.

Onderzoeksopzet

Blood samples are drawn during each study period, from 1 h before until 6 h after test meal consumption, via a venous catheter. During the whole study period several breath, urine and feces samples will be collected.

Onderzoeksproduct en/of interventie

Volunteers will receive four different test meals on separate days (at least 1 week interval). The test meals are:

1. Pasta;

2. Control bread;

3. High GI bread;

4. Low GI bread.

With the test meals 10 mg diet-halvarine, 2 slices lean ham and 250 mL of water will be provided. The test products will be made from wheat flour/kernels, wheat bran, water, yeast and salt. The breads will have a similar composition, but will be differently processed. Each test meal will provide 50 g of available carbohydrate.

The test meals are enriched with the stable isotope 13C and volunteers are infused with a tracer amount of the stable isotope 2H for 8 h (6 h postprandial). This method called the 'dual isotope technique' is used in order to calculate glucose kinetics. Blood samples are drawn during the study period via a venous catheter and several breath and urine samples will be collected.

Contactpersonen

Publiek

University Medical Center Groningen (UMCG)
Antonius Deusinglaan 1
M.G. Priebe
Building 3215 4th floor
Groningen 9713 AV
The Netherlands
+31 (0)50 3619386

Wetenschappelijk

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Antonius Deusinglaan 1
M.G. Priebe
Building 3215 4th floor
Groningen 9713 AV
The Netherlands
+31 (0)50 3619386

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy male volunteer (at least 18 y old);

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. Stable weight and no intention to lose weight until completion of the study;

5. Signed written informed consent form (ICF).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

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

3. Diabetes mellitus;

4. Gastrointestinal disorders (including constipation);

5. Undergone digestive tract surgery (except appendectomy);

6. Stool frequency of less than 3 times a week;

7. Clinically significant inflammatory disease (possibly interfering with measurement of parameters in this study);

8. 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);

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

10. Donation of blood within the last 3 months prior to admission to the clinic;

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

12. Positive drug screen or alcohol breath test at D-1.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	14-09-2011
Aantal proefpersonen:	10
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	10-08-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2875
NTR-old	NTR3020
Ander register	Protocol ID : 104958-CS0168
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A