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

No registrations found.

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

Summary

ID

NL-OMON21832

Source
NTR

Brief title
TIFN2

Health condition

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

Sponsors and support

Primary sponsor: Top Institute Food and Nutrition (TIFN)
Source(s) of monetary or material Support: Top Institute Food and Nutrition (TIFN)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

The secondary study parameters are plasma concentrations of incretins. Metabolomic analysis will be performed in plasma and urine samples. In breath samples 13CO2 will be measured. In feces samples incorporation of 13C in intestinal microbes (after Low GI bread) will be determined. Sensation of appetite and satiety (VAS) after consumption of the test meal is also considered as a secondary parameter.

Other study parameters include body weight, BMI, family history of T2DM, habitual diet, smoking habits, sportive activities, the liking of the test meal (VAS) as well as feeling and extent of discomfort after consumption of the test meal.

Study description

Background summary

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).

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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

Eligibility criteria

Inclusion criteria

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).

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-09-2011
Enrollment:	10
Type:	Actual

Ethics review

Positive opinion

Date:	10-08-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results

Summary results
N/A