

The glycemic index of different grain based foods in healthy volunteers.

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38892

Source

ToetsingOnline

Brief title

GI-Grain based foods

Condition

- Other condition

Synonym

n.a.

Health condition

n.v.t.

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W, Peijnenburg, Student internship grant van Peijnenburg (bedrijf; zie G2)

Intervention

Keyword: Carbohydrate, Glycemic index, Glycemic response, Whole grain

Outcome measures

Primary outcome

Blood glucose response after consumption of the test products (2 grain-based baked food products and white bread).

Secondary outcome

Related effects (of the glucose responses) on subjective ratings of hunger and satiety.

Correlation between the obtained in vivo data and in vitro digestion data resulting from trials at TNO-Zeist.

Study description

Background summary

Whole grain foods thought to be low glycemic, and able to decrease the glycemic load of meals. Addition of food fibers (aleurone, beta-glucans) is expected to further reduce the glycemic response and is also expected to impact on hunger and satiety feelings.

Study objective

The objective of the current study is to evaluate and compare the glucose responses after consumption of each of the 2 whole grain foods (2 types of 'ontbijtkoek') and white bread. Furthermore, related effects (of the glucose

responses) on subjective measures of satiety and hunger will be evaluated. Furthermore, we aim to study the correlation between the obtained in vivo data (current study) and in vitro digestion data resulting from trials at TNO-Zeist.

Study design

The current study will be executed conform a randomized, cross-over, reference-controlled, study design. During the glycaemic response test days, 3 test products (including white wheat bread as control) will be tested on 3 separate test days. The order in which the test products will be presented to participants will be randomized by a statistician. Glucose responses to each of the test products will be measured by obtaining blood samples before ($t = 0$) and after administration of the test products ($t = 15, 30, 45, 60, 90, 120, 150$ min).

Intervention

Participants will be provided with different test products at the start of each test day, namely 2 different types of 'Ontbijtkoek' and white bread. They will be provided in a random order. The glucose response to each of these test products will be measured during each test day, as well as participants' subjective ratings of hunger and satiety.

Study burden and risks

All participants who will be recruited for this study are healthy and not suffering from any diseases that put them at risk during the course of this research. Furthermore, as mentioned before, all foods tested in this study are made for human consumption, according to standard food production procedures. All ingredients used in these foods are food grade and commonly used in the Dutch food industry. So there are no risks concerning the test products.

Concerning the blood sampling there are minor usual risks as always present during needle insertion and sampling moments.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Blood pressure: diastolic blood pressure between 60 and 90 mmHg and a systolic blood pressure between 100 and 150 mmHg
- Body Mass Index (BMI; weight/length²) between 18 and 25 kg/m²
- Protein and glucose are not allowed to be present in urine that will be collected during screening.
- Subjects have to be healthy (self reported) and are not allowed to use medication that can interfere with the current study.
- Normal Dutch dietary eating habits (no vegan, vegetarian or macrobiotic lifestyle)

Exclusion criteria

- Having a history of medical or surgical events that may significantly affect the study outcome (gastro-intestinal diseases)
- Any current metabolic or endocrine disease
- Diabetes Mellitus (type I and II)
- More than 28 consumptions of alcohol a week (for men) and more than 21 consumptions of alcohol a week (for women)
- Reported intolerance for gluten
- Having regularly gastro-intestinal complaints (stomach upsets, diarrhea, constipation, wind, abdominal colic)
- Reported unexplained weight loss or gain of >2kg in the month prior to the pre-study

screening

- Reported slimming or medically prescribed diet
- Reported vegan, vegetarian or macrobiotic lifestyle
- Use of antibiotics during the last three months
- Pregnant or lactating or wishing to become pregnant in the period of the study
- currently in menopause / post-menopausal
- The following drugs are not allowed during the study:
 1. Anti-hypertensive drugs
 2. Lipid lowering-drugs
 3. Glucose-lowering agents.
 4. Anti-inflammatory agents
 5. Chronic oral or parenteral corticosteroids treatment (> 7 consecutive days of treatment).
 6. Laxatives, antibiotics, anti-diarrhea drugs

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	14
Type:	Anticipated

Ethics review

Approved WMO	
Date:	06-11-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29362

Source: Nationaal Trial Register

Title:

In other registers

Register ID

CCMO NL43759.068.13

Other We hebben het onderzoeksprotocol bij het NTR geregistreerd maar tot op heden nog geen NTR nummer ontvangen - jullie krijgen dit zodra wij een nummer hebben

OMON NL-OMON29362