De glycaemische index van verschillende graanproducten bij gezonde vrijwilligers.

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(1) The ‘Ontbijtkoek’ based on teff yields a lower glycemic response (has a lower GI) than the ‘Ontbijtkoek’ based on rye and both ‘Ontbijtkoeken’ will yield a lower glycemic response than the reference test product, white bread; (2) The ‘…

Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29362

Bron
Nationaal Trial Register

Verkorte titel
GI-GBF

Aandoening

N/A
We will study healthy subjects (healthy BMI, not suffering from metabolic diseases / diabetes / obesity / gastrointestinal disorders) and investigate the blood glucose response to three different grain based foods.

Ondersteuning

Primaire sponsor: Maastricht University
Overige ondersteuning: Student internship grant from Peijnenburg NL

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The post-prrandial glucose response and glycaemic index after consumption of all 3 above named test products (2 types of ‘Ontbijtkoek’ differing in grain flour composition and the reference product, white bread).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Whole grain foods are thought to be low glycaemic compared to refined flour foods. Since cereal types differ in composition of the type of starch, fibre and protein content, it is expected that the use of different flour types will result in difference in digestion, absorption and consequently glycaemic response.
The glycaemic response of foods, as well as the related glycaemic index (GI), may be predicted based on results obtained from “in vitro digestion’ using the Tiny TIM model, developed by TNO (Zeist, the Netherlands). In order to justify that the in vitro data truly reflect the in vivo data, both tests should be executed and correlations should be calculated. In the present overall research project the in vitro measurements will be executed by TNO.. The human in vivo experiments are here proposed to be executed at Maastricht University. Accordingly, the current study focuses on the effects of 2 types of ‘Ontbijtkoek’ differing in whole grain flour composition and white bread on the glycaemic response in health human volunteers. Since glycaemic response is known to impact on feelings of hunger and satiety, the subjective feelings of hunger and satiety will be scored in addition.

Objective: To study the effect of 3 different baked foods (white bread and ‘Ontbijtkoek’ containing either rye or teff flour) on blood glucose responses in vivo, to allow for validation of the results obtained in vitro. Additionally, feelings of hunger and satiety in response to these test products will be obtained.

Study design: The study will be executed conform a randomized; cross-over, reference-controlled study design.

Study population: 14 healthy male and female participants, between 18 and 50 years of age, will be recruited.

Intervention: Participants will receive each of 3 test baked test foods (2 types of ‘Ontbijtkoek’ differing in grain flour composition and white bread), randomly on 3 separate test days. In order to avoid differences in product composition, we will use products from a single baked batch. All products will be deep-frozen and used upon daily needs.

Main study parameters/endpoints: The main study parameter is the glucose response curve of all test products. Other important parameters are satiety/hunger scores - based on a subjective rating scale – in response to all test foods.

Doel van het onderzoek

(1) The ‘Ontbijtkoek’ based on teff yields a lower glycemic response (has a lower GI) than the ‘Ontbijtkoek’ based on rye and both ‘Ontbijtkoeken’ will yield a lower glycemic response than the reference test product, white bread;
(2) The ‘Ontbijtkoek’ based on teff exerts a more positive (or prolonged) effect on measures of hunger and satiety than the ‘Ontbijtkoek’ with a higher glycemic response. Furthermore, it is expected that both types of ‘Ontbijtkoek’ will have more positive effects on measures of hunger and satiety when compared to the reference test product, white bread.
(3) The calculated in vitro glycemic responses the test products are similar to the in vivo measured responses.

Onderzoeksopzet

Blood samples to measure blood glucose levels will be obtained at -5, 15, 30, 45, 60, 90, 120 and 150 minutes relative to consumption of one of the test products. Participants will be asked to complete a questionnaire to obtain subjective measures of hunger and satiety prior to each blood sampling.

Onderzoeksproduct en/of interventie

Participants will receive 2 types of ‘Ontbijtkoek’ - differing in grain flour composition: rye or teff - and white bread (reference product) randomly on 3 separate test days.

Contactpersonen

Publiek

[default]
The Netherlands

Wetenschappelijk

[default]
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

Measured during screening:
• 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
• Subjects have to be healthy (self reported – a score of 4/5 out of 5 on the screening questionnaire) and are not allowed to use medication
that can interfere with the current study (drugs that are not allowed during the study are listed in section 4.3 Exclusion criteria).
• Master the Dutch language (as VAS questionnaires are in Dutch)
• Fasted blood glucose has to be < 7.1 mmol/L.

Furthermore, the subjects must have:
• Normal Dutch dietary eating habits (no vegetarian, vegan or macrobiotic lifestyle)
• To participate voluntary (give written informed consent)
• To be willing to comply with the study procedures
• To be willing to accept use and storage of all data, publication of nameless data
• To be willing to accept the disclosure of the financial benefit to participation in the study to the authorities concerned.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Recent participation in any clinical trial (<30 days)
• 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
• Smoking
• Pregnant or lactating or wishing to become pregnant in the period of the study
• Not having a general practitioner
• Not willing to accept information-transfer concerning participation in the study, or information regarding health of the subject, like findings at anamnesis or physical

examination and eventual adverse events to and from general practitioner
• The subject will be excluded from the study if he / she does not want to be informed about deviating findings / accidental findings concerning his / her health
• 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-12-2013
Aantal proefpersonen:	14
Type:	Onbekend

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38892
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4037
NTR-old	NTR4203
CCMO	NL43759.068.13
OMON	NL-OMON38892

Resultaten