

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

Submission date 15/11/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 10/01/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 18/12/2020	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RV/TIFNC1

Study information

Scientific Title

Slow starch foods: an explorative pilot study - postprandial glucose kinetics and metabolic effects of different wheat products in healthy men

Study objectives

It was hypothesised that the consumption of wheat pasta and wheat bread with purple fibre would result in different postprandial glucose kinetics and would have a beneficial effect on several parameters involved in the pathogenesis of insulin resistance and Type 2 Diabetes Mellitus (T2DM) as compared to the consumption of a wheat bread with normal fibre.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical Ethics Committee of the BEBO foundation, Assen, The Netherlands approved on the 8th January 2009 (ref: CCMO NL 26384.056.08; study code 080290-CS0127)

Study design

Single centre randomised crossover study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Insulin resistance/type 2 diabetes mellitus

Interventions

Ten healthy male volunteers will participate in the study, receiving three different test meals on three separate days (at least 1 week interval). The test meals are:

1. White wheat bread with fibre from normal wheat
2. Wheat pasta with fibre from normal wheat
3. White wheat bread with fibre from purple wheat

Purple wheat fiber added to white bread might result in a slower starch digestion. Purple wheat contains a high amount of anthocyanins, which are found in vitro to have the ability to inhibit α -amylase and α -glucosidase.

The test meals are enriched with the stable isotope ^{13}C and volunteers are infused with a tracer amount of the stable isotope ^2H for 8h. 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.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Glucose kinetics of the test meals, such as the rate of appearance of exogenous glucose in plasma. Glucose kinetics is calculated using total plasma glucose concentration, the $^{13}\text{C}/^{12}\text{C}$ -ratio of glucose in plasma samples, and the $^2\text{H}/^1\text{H}$ -glucose ratio in plasma samples.

Plasma samples were drawn at the following timepoints (in minutes, at $t = 0$ the test meal was consumed): -60, -30, 0, 15, 30, 45, 60, 75, 90, 105, 120, 150, 180, 210, 240, 270, 300, 330, 360.

Plasma concentrations of total blood glucose and insulin are also considered as primary outcome measures.

Secondary outcome measures

1. Plasma concentrations of incretins and markers of inflammation
2. Sensation of appetite and satiety (VAS registration) as well as feeling and extent of discomfort after consumption of the test meal
3. Demographic and other parameters include
 - 3.1. Body weight
 - 3.2. Body mass index (BMI)
 - 3.3. Family history of T2DM
 - 3.4. Habitual diet
 - 3.5. Smoking habits
 - 3.6. Sportive activities

Overall study start date

01/12/2008

Completion date

05/02/2009

Eligibility

Key inclusion criteria

1. Healthy male volunteer aged greater than or equal to 18 years
2. Used to eat breakfast (solid food)

3. Not involved in intensive sportive activities more than once a week (e.g. playing football, tennis, running, race-cycling, swimming)
4. Stable weight and no intention to loose weight until completion of the study

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

10 healthy male volunteers

Total final enrolment

10

Key exclusion criteria

1. Diabetes mellitus
2. Gastrointestinal disorders (including constipation)
3. Body mass index (BMI) less than 18 or greater than 25 kg/m²
4. Not being able to fast overnight (12 hours)
5. Intake of medication
6. Undergone digestive tract surgery (except appendectomy)
7. Inflammatory disease (possibly interfering with measurement of parameters in this study)
8. Donation of blood (greater than 500 ml) within the last 3 months prior to admission to the clinic
9. Participation to another clinical study within 90 days before enrolment

Date of first enrolment

01/12/2008

Date of final enrolment

05/02/2009

Locations**Countries of recruitment**

Netherlands

Study participating centre

Center for Medical Biomix
Groningen
Netherlands
9713 AV

Sponsor information

Organisation

Top Institute Food and Nutrition (TIFN) (Netherlands)

Sponsor details

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Sponsor type

Industry

Website

<http://www.tifn.nl/>

ROR

<https://ror.org/0183vre95>

Funder(s)

Funder type

Research organisation

Funder Name

Top Institute Food and Nutrition (TIFN) (Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2012	18/12/2020	Yes	No
Results article	results	01/02/2017	18/12/2020	Yes	No
Results article	sub study results	01/02/2012	18/12/2020	Yes	No