ISRCTN42106325 https://doi.org/10.1186/ISRCTN42106325

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

| Submission date | Recruitment status |
|---|---|
| 15/11/2010 | No longer recruiting |
| **Registration date** | **Overall study status** |
| 10/01/2011 | Completed |
| **Last Edited** | **Condition category** |
| 18/12/2020 | Nutritional, Metabolic, Endocrine |

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Marion Priebe

**Contact details**
Center for Medical Biomics
University Medical Center Groningen (UMCG)
Antonius Deusinglaan 1
Groningen
Netherlands
9713 AV

## 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 fibrer 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 13C 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 13C/12C-ratio of glucose in plasma samples, and the 2H/1H-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 Biomics**
Groningen
Netherlands
9713 AV

# Sponsor information

**Organisation**
Top Institute Food and Nutrition (TIFN) (Netherlands)

**Sponsor details**
c/o M. G. Priebe
Center for Medical Biomics
University Medical Center Groningen (UMCG)
Antonius Deusinglaan 1
Groningen
Netherlands
9713 AV

**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 |