Prebiotic fibre study

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23115

Source
Nationaal Trial Register

Health condition

Obesity, Gastrointestinal Health, Metabolic Health

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: na

Intervention

Outcome measures

Primary outcome

Whole gut transit time

Secondary outcome

Markers of gastrointestinal health

Study description

Study objective

Dietary fibre intake provides many health benefits. A sufficient or generous intake of dietary fibre reduces the risk for developing coronary heart disease, stroke, hypertension, diabetes, obesity and certain gastro-intestinal disorders. Increased consumption of dietary fibre has been shown to improve serum lipid concentrations, reduced blood pressure, improve blood glucose control in diabetes, promotes regularity, helps in losing weight and improves immune function [1]. The most pronounced effect of dietary fibers is on gastrointestinal transit (GI) time and fecal bulking, attributed mostly to insoluble, non-fermentable dietary fibers such as wheat bran. GI transit is an important parameter of gut health relevant for many physiological and metabolic processes. Other dietary fibers such as soluble and fermentable fibers function as prebiotics, which are fermented in the colon and thus positively affect microbiota composition and activity. However, little is known about effect of prebiotic fibers on gastrointestinal transit and the metabolic consequences. Additionally, potential shifts in the microbiome have not been evaluated at a large scale with ‘state-of the art’ metagenomic profiling techniques. In this study, we investigate the effect of prebiotic fiber arabinoxylan-oligosaccharides (AXOS) on gastrointestinal transit time and markers of gut health and relate them to the metabolic parameters. Integrating gut physiology and microbiome with host parameters of systemic inflammation, glucose, lipid and energy metabolism would yield unique new insights that may hold great relevance in the prevention of chronic metabolic diseases. This is of particular relevance for the wheat bran derived arabinoxylans, which have been reported to have a distinct effect on short chain fatty acid (SCFA) production by the microbiota, and affect satiety and glycemic and insulinemic profiles in the human host.

Study design

Markers of metabolic health

Intervention

1. Wheat-derived, Arabinoxylan-oligosaccharides (AXOS)

15g/day ingested with the meals (5 g in beverage, to be consumed three times a day)

2. Placebo: maltodextrin

15g/day ingested with the meals (5 g in beverage, to be consumed three times a day)

Contacts

Public

Muller
Maastricht
The Netherlands
Scientific
Muller
Maastricht
The Netherlands

Eligibility criteria

Inclusion criteria

Overweight to obese men and women (BMI ≥ 25 kg/m2 <35 kg/m2)

- Aged 20-50 years

- Caucasian

- Normal fasting glucose (<6.1 mmol/L.)

- Normal blood pressure (systolic blood pressure 100-140 mmHg, diastolic blood pressure 60-90 mmHg)

- Weight stable in last 3 months (±2 kg)

- A low defecation frequency, <3 times/week and no constipation or underlying pathology, as determined by gastro-intestinal questionnaires).

- A low whole gut transit

Exclusion criteria

4.3 Exclusion criteria

- Woman lactating, pregnant (where pregnancy is defined as the state of a female after conception and until the termination of gestation, confirmed by a positive hCG laboratory test) or (post)-menopausal

- Regular smokers

- People with intensive fitness training, eg. athletes (≥3 per week ≥ 1 hour training)

- Diabetes Mellitus (defined as FPG ≥ 7.0 mmol/l and or 2h PG ≥ 11.1 mmol/l)

- Gastro-intestinal diseases or abdominal surgery, cardiovascular diseases, cancer, liver or kidney malfunctioning (determined based on ALAT and creatinine levels, respectively) disease with a life expectation shorter than 5 years

- Following a hypocaloric diet

- Gluten intolerance

- Regular use of laxation products, or use of antibiotics, probiotics or prebiotics 3 months prior to the start of the study

- More than 2 symptoms occurring over a period of 12 weeks in the preceding 12 months such as

(1) Straining in >1/4 defecations;

(2) Lumpy or hard stools in >1/4 defecations;

(3) Sensation of incomplete evacuation in >1/4 defecations;

(4) Sensation of anorectal obstruction/blockade in >1/4 defecations

(5) Manual maneuvers to facilitate >1/4 defecations (e.g., digital evacuation, support of the pelvic floor); and/or

(6) <3 defecations/week

- Current use of medication interfering with study intervention or interfering with study endpoints/hypotheses

- Not to be able to understand the study information

- Blood donation 2 months prior to the study and during the study

- Participation in other studies

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2015
Enrollment:	50
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 42114
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4847
NTR-old	NTR5102
CCMO	NL52300.068.15
OMON	NL-OMON42114

Study results