FiberKinetics2 study: A feasibility study on fiber fermentation, and short chain fatty acid kinetics and utilization inside the gut and systemic circulation

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49956

Source
ToetsingOnline

Brief title
FiberKinetics2

Condition

- Other condition

Synonym
microbial activity, products of gut bacteria

Health condition

de darm: microbiota compositie activiteit en microbiële producten

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: NWO

Intervention

Keyword: dietary fiber, Metabolism, microbiota, SCFA (short chain fatty acids)

Outcome measures

Primary outcome

- To show placement of a naso-intestinal catheter in the proximal colon, and

sampling in this intestinal region.

- (The effect of NDC on) intestine luminal NDC and its degradation products

SCFA. Also (13C label incorporation in) plasma metabolic markers such as

organic acids, amino acids, glucose, cholesterol, fatty acids and bile acids.

- To investigate if intake of dietary fiber for a couple of days will effect

in vivo acute fiber fermentation.

Secondary outcome

Intestinal lumen microbiota and activity after NDC bolus.

Study description

Background summary

Nowadays there is a strong interest in optimising human health through manipulation of non-digestible carbohydrates (NDC). NDC can be used as substrates by gut microbiota, which results in NDC degradation, production of fermentation products, such as short-chain fatty acids (SCFA), and a shift in microbiome composition and activity. It is hypothesized that SCFAs mediate parts of the beneficial effects of NDC. In mice, the influx of SCFA into the host correlated strongly with improvements of markers of the metabolic

syndrome, in contrast to the concentrations of SCFA in the cecum. Therefore, the influx of short chain fatty acids (SCFA) into the body may be of high importance in improving metabolism. There is a need for more studies in humans to trace the life course of SCFA and their regulatory role in human metabolism. To study this inner world of bacterial products in humans, we will use a nasal-intestine catheter that can be used for delivery of components and sampling intestinal chyme.

Study objective

In this pilot study we will investigate the acute fermentation of fructo- and galacto-oligosaccharides in the proximal colon. Moreover, we will deliver 13C-labelled SCFA via a naso-intestinal catheter to quantify the fluxes of SCFA production, interconversion and uptake by the host.

Study design

a small-scale, 7-day parallel feasibility trial, N=5 subjects will receive GOS/FOS supplements (mix 1:1 ratio, 15 gram/day), and N=5 other subjects will receive placebo supplements (isocaloric maltodextrin, 13.4 gram/day). At the last day of the supplementation period, the catheter will be placed, and afterwards participants stay maximum 5 hours in the hospital, to ensure progression of the nose-intestine catheter. After an overnight fast, subjects will visit the hospital again for measurements. A cannula for blood sampling is placed. Subjects will consume a NDC bolus (200 mL tap water, 5 gram fructo-oligosaccharides, 5 gram galacto-oligosaccharides, non-absorbable marker (PEG-4000). Afterwards, they are not allowed to eat for 6.5 hours. Isotopically 13C-labelled SCFAs will be delivered in the proximal colon. Blood and intestinal samples will be collected during the day, up to 390 minutes. Breath samples, faeces and urine will also be collected.

Intervention

7 days FOS/GOS (15 gram/day) or 7 days maltodextrin (13.4 gram/day). NDC bolus: 200 mL tap water, 5 gram fructo-oligosaccharides, 5 gram galacto-oligosaccharides, non-absorbable marker PEG-4000.

Study burden and risks

Subjects that participate in this study will invest approximately 15 hours. The subjects will perceive mild discomfort during the placement of the catheter. The radiation exposure is minimal (max. 0.05-0.10 mSv) and induces no health risk to the healthy subjects. In case of structural complains we will council our medical supervisor. The GOS and FOS present in the NDC bolus are commercially available and of food-grade quality (provided by FrieslandCampina and Sensus B.V. en AVEBE). During the test day (takes around 8 hours) we will

collect 200 mL of blood. The Hb value of each participants will be checked. Participants will have to visit the Hospital Gelderse vallei at two occasions. Participants will receive ¤320,- after completion of the study, they will also receive a repayment of traveling expenditures for the visit.

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

* Males
* Age 18-60yrs
* BMI between 18.5 and 30 kg/m2
* Regular bowel movement (defaecation on average once a day)
* Signed informed consent

Exclusion criteria

* Having a history of medical or surgical events that, in the opinion of the Investigator, may either put the subject at risk because of participation in the study, or influence the results of the study (e.g. diabetes, cardiovascular disease, gastrointestinal disease, renal failure, cancer, infectious disease, nose/throat).
* Having a history of surgical events of the gastro-intestinal tract (e.g. bariatric surgery/gastric bypass surgery)
* Presence of swallowing disorder
* Use of any prescribed or non-prescribed medication (other than paracetamol) including antacids, analgesics, and herbal remedies during the three (3) weeks prior to study start.
* Being lactose intolerant
* Follows a vegan diet
* Use of antibiotics within 3 months of starting the study or planned during the study
* Use of pro- or prebiotics (e.g. galacto-oligosaccharides, fructo-oligosaccharides)
* Constipation/infrequent bowel movement (less than 3 times defaecation per week)
* Abuse of drugs/alcohol (alcohol: >4 consumptions/day or >21 consumptions/week)
* Smoker
* Having diarrhoea within 1 month prior to the study start
* Personnel of Wageningen University, Division of Human Nutrition, their partner and their first and second degree relatives
* Participation in another biomedical study or other research from the Division of Human Nutrition
* Not willing to be exposed to fluoroscopy
* Is sensitive for iodinated components
* Having a hemoglobin of <8.5 mmol/L
* Having blood vessels that are too difficult for inserting a cannula
* Not having a general practitioner

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-10-2020
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	naso-intestinal catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	25-09-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT04499183
CCMO	NL74418.081.20