FiberKinetics study:
The study of fiber fermentation, 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	Observational invasive

Summary

ID

NL-OMON48396

Source
ToetsingOnline

Brief title
FiberKinetics-study

Condition

- Other condition

Synonym
microbial activity, products of gut bacteria

Health condition

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: Metabolism, SCFA (short chain fatty acids), stable isotope tracers

Outcome measures

Primary outcome

Main study parameters/endpoints: (isotopic) enrichments of SCFAs (in the cecum and blood), and plasma organic acids, glucose, cholesterol, fatty acids

Secondary outcome

Blood markers for microbial activity: Markers of specific microbial group activity that can be related to the host health status, like organic acids, hippurate, di- en tri-methylamine, acetaldehydes, glucuronic acid conjugates, and bile acid (conjugates).

Bacterial activity/microbiota composition in luminal samples.

Fibre degradation: To study acute fibre breakdown, the fibre degradation products, including mono-, di-, tri-, oligo- and polysaccharides.

Urine metabolic profiles: A fasting urine sample will be collected before at the start of the test day and at the end of the test day. Urine samples will be analysed to analyse bile acids, organic acids, aminoa cids, including bacterial

products and their taurine, glycine, and glucuronic acid conjugates.

Study description

Background summary

Nowadays there is a strong interest in optimising human health through manipulation of non-digestible carbohydrates (NDC). NDC are fermented by the microbiota, hereby producing fermentation end products, mainly short chain fatty acids (SCFA) acetate, butyrate, and propionate. 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, whereas concentrations of SCFA in the cecum did not. 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 of intestinal chyme.

Study objective

In this pilot study we have technical/methodological questions: we want to confirm the envisioned kinetic profiles of stable isotope tracers 13C-labelled SCFA delivered by catheter in 5 subjects, and to establish the time points of plasma sampling (to determine systemic availability of SCFAs). Additionally, we want to test the proper time delay between delivery, and sampling of 13C-labelled SCFAs inside the cecum using the same catheter, to study interconversions of SCFA in the human gut. The resulting timepoints established in this pilot study will be applied during a future human intervention study in which the impact of a contrast in dietary NDC will be investigated.

Study design

In the cecum isotopically 13C-labelled SCFAs will be delivered, afterwards at different time points samples will be taken from the cecum and blood. In short: at day 1 the catheter will be placed, and afterwards participants stay maximum 7 hours in the hospital, to ensure progression of the nose-intestine catheter towards the distal small intestine. After an overnight fast at day 2, 5 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 8 hours. When fermentation has started, isotopically 13C-labelled SCFAs will be delivered in the cecum. Thereafter, production and inter-conversion of SCFAs and breakdown

of fiber, will be studied in luminal samples that will be taken every 30 min to determine SCFA cross-feeding. We sample in the cecum at different times to select the best time point to study cross-feeding in the final human intervention study. Blood samples will be collected from a cannula before, and continuously after dispensing the 13C-labelled SCFAs.

Intervention

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 23.5 hours. The subjects will perceive mild discomfort during the placement of the catheter. The radiation exposure is minimal (0.12 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.). During the test day (takes around 12 hours) we will collect 200ml of blood. The Hb value of each participants will be checked before blood collection. 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, and for the screening ¤10.

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.
• Use of cholesterol lowering medication
• Carrying a pacemaker or any other (implanted) medical electronic device
• Smoker
• Unstable body weight (weight gain or loss >5kg in the past 3 months prior to the study start)
• 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
• Abuse of drugs/alcohol (alcohol: >4 consumptions/day or >21 consumptions/week)
• Participation in another biomedical study
• Having diarrhoea within 2 months prior to the study start
• Personnel of Wageningen University, Division of Human Nutrition, their partner and their first and second degree relatives
• Current participation in other research from the Division of Human Nutrition
• Not willing to undergo fluoroscopy
• Having blood vessels that are too difficult for inserting a venflon
* Having a hemoglobin of <8.4 mmol/L

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-07-2019
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	26-06-2019
Application type:	First submission

Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	14-10-2019
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)

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
CCMO	NL69449.081.19