HealThy fAt, haPpy mIcRobiome - Proof-of-Concept Study

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To assess the effect of dietary lipids on the small intestinal microbiome in humans (proof-of-concept), the primary objective is to measure production of microbiota-derived lipid metabolites in the human small intestine after consumption of a high-...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53617

Source
ToetsingOnline

Brief title
TAPIR

Condition

- Other condition
- Lipid metabolism disorders

Synonym
digestion, microbial fermentation

Health condition

vertering en microbioom

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: AAK,Bioiberica,Cargill,Novozymes,Topsector voor kennis en innovatie (TKI),Upfield

Intervention

Keyword: dietary lipids, microbiome, small intestine

Outcome measures

Primary outcome

The primary study parameters are the microbial-derived metabolites from

linoleic acid and plant sterols after consumption of the high fat shake.

Secondary outcome

Secondary study parameters include microbiota composition and transcriptomic

activity. Other outcomes include inflammatory markers and ex-vivo analyses.

Study description

Background summary

The role of dietary lipids in host-microbiome research has for a long time been overlooked, as high lipid intake has been recently indicated to have the most pronounced effect on the small intestinal microbiome, hence fecal-oriented studies might have missed their important, local effect. Many of the uniquely formed metabolites still have to be accurately described, and even so their biological function, including e.g. potential anti-obesity and immune effects, remains to be elucidated. This study therefore aims at exploring this principal in vivo in healthy individuals.

Study objective

To assess the effect of dietary lipids on the small intestinal microbiome in humans (proof-of-concept), the primary objective is to measure production of microbiota-derived lipid metabolites in the human small intestine after consumption of a high-fat shake in healthy pre-conditioned subjects.
The secondary objectives are 1) To compare the microbiota-derived lipid

metabolites in aspirate samples obtained with a naso-intestinal catheter (golden standard; invasive sampling method), and an aspiration capsule (less invasive, innovative sampling method), and in blood (local versus systemic effect) and feces (small intestinal versus fecal effect; less invasive sampling); 2) To investigate the acute effect of a high-fat shake on the composition and transcriptomic activity of the small intestine microbiota in aspirate samples of healthy pre-conditioned subjects; 2a) To compare the acute effects on the small intestine microbiota composition in aspirate samples obtained through a naso-intestinal catheter versus those obtained via an aspiration capsule; 3) To study and compare the effect of a plant-based mild ketogenic preconditioning diet on the composition of the small intestinal microbiota (aspiration capsule) and the fecal microbiota.

Study design

Proof-of-concept intervention study

Intervention

8-days preconditioning mild ketogenic controlled diet followed by a high fat shake challenge with a naso-intestinal catheter.

Study burden and risks

This study is related to a broad general population. There are minor risks for the healthy research subjects of this study. Placement of the naso-intestinal catheter can result in discomfort. The radiation exposure during placement is minimal (maximum 0.05-0.10 mSv) and induces a minimal health risk to the healthy subjects. Consumption of the mild ketogenic diet and the liquid high-fat shake may cause gastro-intestinal discomfort. Blood sampling will be performed via a cannula and the insertion can be painful and may cause a bruise. The amount of blood that is drawn from subjects is within acceptable limits (total amount collected = 89mL). Research subjects will invest approximately 22 hours in the study. They will visit the research facility 6 times: short screening, capsule and preconditioning diet pick-up, naso-intestinal catheter insertion, high-fat shake challenge test day, and fecal sample hand-in (2x).

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

- Male or female adults
- BMI 18.5-30 kg/m2
- Suitable veins for insertion of cannula

Exclusion criteria

- Having a history of medical or surgical events that may either put the subject at risk because of participation in the study, or influence the results of the study, including diabetes mellitus, a swallowing disorder, gastrointestinal or liver disease, dyslipidemia, sleeping apnea, irritable bowel syndrome, renal failure, cancer, nose/throat diseases, gastric bypass surgery, use of anticoagulants; as determined by the medical supervisor;
- Having a bleeding/coagulation disorder, including hemophilia, Von Willebrand disease, Bernard-Soulier, Glanzmann thrombasthenia or thrombocytopenia;
- Use of antibiotics within 3 months of starting the study or planned during the study;
- Use of medications known to interfere with gastro-intestinal function (e.g. gastric acid inhibitors), as determined by medical supervisor;

- Use of pro- and prebiotic supplements within 4 weeks of starting the study; - Planning or scheduled to undergo magnetic resonance imaging (MRI) at any time during the course of the study - Currently following a very low carbohydrate (ketogenic) diet;
- Alcohol consumption >21 glasses a week (women) or >28 glasses a week (men);
- Pregnant, lactating or wishing to become pregnant in the period of the study (self-reported);
- Not willing to give up blood donation during the study;
- Food allergies or intolerances for products that we use in the study;
- Current smokers;
- Current users of soft and/or hard drugs;
- Participation in another clinical trial at the same time;
- Having fewer than three bowel movements per week (having constipation)
- Being an employee of the Food, Health & Consumer Research group of Wageningen Food & Biobased Research or Human Nutrition and Health Department of Wageningen University.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	04-10-2023
Enrollment:	16
Type:	Actual

Medical products/devices used

Generic name:	Small Intestine MicroBiome Aspiration Capsule (SIMBA)
Registration:	No

Ethics review

Approved WMO Date:	01-08-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL81345.091.23
Other	Volgt nog