Comparing food-induced gut microbiome shifts in vitro and in vivo

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To support the validity of an in vitro colonic fermentation system, by demonstrating that changes in gut microbiota composition and functionality/metabolism, induced by prebiotics in the in vitro Microcolon model, are mimicking the changes that are...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56821

Source
ToetsingOnline

Brief title
MAGIC Study

Condition

- Other condition

Synonym
shift in gut microbiome

Health condition

small and large intestinal microbiome in healthy subjects

Research involving
Human

Sponsors and support

Primary sponsor: NIZO food research B.V.
Source(s) of monetary or material Support: NIZO food research

Intervention

Keyword: ex vivo assay, gut microbiome, validation

Outcome measures

Primary outcome

Changes in gut microbiota composition (comparison between in vitro MicroColon model and in vivo human results). Composition changes of interest will include Bifidobacterium (genus), Bifidobacterium species, Lactobacillaceae (family), Parabacteroides distasonis , Anaerobutyricum hallii and Faecalibacterium prausnitzii.

Secondary outcome

More general changes in microbiota composition, diversity and functionality (comparison between in vitro MicroColon model and in vivo human results).

Explorative outcomes include the practical application (logistics, feasibility, acceptability) of a small intestinal sampling capsule in vivo and the comparison of small intestinal microbiome with fecal microbiome, at the individual level.

Study description

Background summary

At NIZO, the so-called MicroColon model has been developed over the last

decade. This miniaturized fermentation model is used to evaluate the interaction of the gut microbiome (from fresh human fecal samples) with food ingredients. However, results of interventions in this in vitro model have not yet been directly compared with the same interventions in vivo.
Therefore we propose to perform a study in healthy human volunteers, in which the short-term in vitro effects of specific ingredients on the gut microbiota composition and functionality in the MicroColon will be compared with the effects of consumption of these same ingredients on gut microbiota composition and functionality in a human study.

Study objective

To support the validity of an in vitro colonic fermentation system, by demonstrating that changes in gut microbiota composition and functionality/metabolism, induced by prebiotics in the in vitro Microcolon model, are mimicking the changes that are observed in a human intervention setting. Secondary objective is to test the application of a small intestinal sampling capsule in vivo.

Study design

The study is designed as an open-label intervention with before-after comparison, with the aim to compare in vivo with in vitro outcomes.

Intervention

Resistant dextrin and 2*-FL (a human milk oligosaccharide) will each be consumed daily in a dose of 10 g by 5 healthy adult volunteers, for a period of 3 weeks.

Study burden and risks

Participants will collect a fecal sample at 2 time points, and they will consume a commercially available dietary fibre supplement for 3 weeks. They will also swallow two sampling capsules, which they will retrieve from their feces. Burden and risks associated with participation are considered small.

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

1. Age >= 18 y
2. Healthy as assessed by general health questionnaire
3. BMI >=18.5 and <=30
4. Regular bowel habits, defined as at least once per 2 days
5. Adherence to habitual diet and lifestyle, no changes during study period
6. Signed informed consent

Exclusion criteria

1. Lower gastrointestinal conditions, such as diarrhea/loose stools or acute gastrointestinal infection in the month before fecal donation, constipation, IBS
2. Diagnosed gastrointestinal disorders (for example, but not limited to, ulcers, IBD, achalasia, eosinophilic esophagitis, hiatus hernia, gastrointestinal cancer diagnosis or treatment within the past year), or previous esophageal, gastric, small intestinal, or colonic surgery; appendectomy or cholecystectomy more than 3 months prior to on-site study visit are acceptable
3. Use of prebiotics or probiotics (an indicative list will be provided) within 4 weeks before fecal donation

4. Use of oral/IV antibiotics in 6 months before fecal donation
5. Fecal Microbiota Transplantation anytime in medical history
6. Use of laxatives within 2 weeks before fecal donation
7. Any clinically significant systemic infection at time of screening
8. Use of medication (for example, but not limited to, opioids, prokinetics, anticholinergics, proton pump inhibitors (PPI)) or dietary supplements that could affect bowel movement / gut motility, or with a history of systemic disease that might affect gut motility according to the investigator; or which could otherwise impact the results of the study
9. History of oropharyngeal dysphagia, or other swallowing disorder with a risk of capsule as-piration
10. History of abdominal radiation treatment
11. Major genital and/or rectum prolapse at the time of screening or other physical abnormali-ties that may impair capsule excretion according to the investigator
12. Alcohol consumption >= 3 units/day
13. Participation in any clinical trial including blood sampling and/or administration of substances starting 1 month prior to study start and during the entire study
14. Pregnancy
15. Not expected to be able to comply with study procedure including SIMBA capsule recovery with - or without help, according to the investigator
16. NIZO employee or first degree relative

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	SIMBA capsule
Registration:	No

Ethics review

Approved WMO Date:	17-06-2024
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
CCMO	NL86394.028.24

Study results

Summary results
Trial never started