The effect of daily consumption of a probiotic drink containing Lactobacillus casei Shirota on the small intestinal microbiota in healthy male subjects as measured by the Intellicap sampling capsule system.

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Primary Exploratory Objective:* To explore the effect of Lactobacillus casei strain Shirota (LcS) on small intestinal microbiota profiles.Secondary Exploratory Objectives:* To explore the differences between the effect of LcS on small intestinal and...

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

Summary

ID

NL-OMON45590

Source
ToetsingOnline

Brief title
ROBIN

Condition

- Other condition

Synonym
Small intestinal microbiota

Health condition

Effect of probiotics on small intestinal microbiota

Research involving
Human

Sponsors and support

Primary sponsor: The Yakult Honsha European Research Center for Microbiology, ESV (YHER)
Source(s) of monetary or material Support: Yakult Honsha European Research Center for Microbiology;ESV (YHER)

Intervention

Keyword: IntelliCap, Microbiota, Probiotics, Small Intestine

Outcome measures

Primary outcome

Microbiota composition in the small intestine (Next Generation Sequencing).

Secondary outcome

Microbiota composition in feces (Next Generation Sequencing), stool frequency,

stool consistency (Bristol Stool Scale), timing of daily behavior,

gastrointestinal symptoms (Gastrointestinal Symptom Rating Scale)

Study description

Background summary

Currently, obtaining samples directly from the small bowel is difficult due to the highly invasive intubation methods used. Research on the effect of dietary probiotics on the gut microbiota is therefore largely dependent on measurement of the microbial composition in fecal samples. At best, the measurement in fecal samples reflects microbial composition of the large intestine.
The microbial composition in the small intestine differs substantially from the composition in feces. In addition, many physiological processes that are modulated by dietary probiotics, such as immunoregulation, mainly occur in the small intestine.
Therefore, it is vital to study the effects of dietary probiotics on the small

intestinal microbiota, as well. Successful sampling of the small intestine has been demonstrated in animals and humans, using the IntelliCap® CR system. This study is explorative in nature. The main aim of the current study is to explore and compare the small intestinal microbiota composition in healthy subjects before and after consumption of a probiotic drink containing Lactobacillus casei strain Shirota (LcS) (Yakult®).

Study objective

Primary Exploratory Objective:
* To explore the effect of Lactobacillus casei strain Shirota (LcS) on small intestinal microbiota profiles.

Secondary Exploratory Objectives:
* To explore the differences between the effect of LcS on small intestinal and fecal microbiota profiles.
* To explore the recovery rate of LcS in the small intestine and feces.
* To investigate the effect of LcS on reported stool frequency, stool consistency (Bristol Stool Scale), and gastrointestinal symptoms (Gastrointestinal Symptom Rating Scale).

Tertiary Exploratory Objectives:
* To assess feasibility of measuring potential biomarkers in the small intestinal sample collected by the IntelliCap® CR capsule: metabolomes (UHPLC-HRMS), organic acids (HPLC), fatty acids (Colorimetric/Fluorometric assay), calcium (Colorimetric assay), defensin (ELISA), and LcS count (PCR) in small intestinal and fecal samples.

Study design

The study is a dietary intervention study with a repeated measures design, comparing the upper GI microbiota composition in healthy male subjects before and after consumption of a probiotic drink containing LcS.

Intervention

Subjects receive dietary guidelines for 37 days (Study day -14 until Study day 23). IntelliCap® CR capsule sampling will be performed at study day 7. At study days 14-20, all subjects will consume 1 probiotic drink containing LcS (Yakult®) daily. A second IntelliCap® CR capsule sampling will be performed at day 21. After IntelliCap® CR capsule sampling, subjects have to collect all stool samples until retrieval of the IntelliCap® CR capsule device.
Subjects have to record stool frequency, stool consistency (Bristol Stool Scale) and timing of daily behavior (wake up-, bed-, meal-, defecation time) and compliance to study guidelines on study day 1-23. On study day 7 and 21, subjects have to record gastrointestinal symptoms (Gastrointestinal Symptom

Rating Scale).

Study burden and risks

The burden of the subjects that participate in this study consist of investing 15 hours in total for screening, dietary guidelines, sampling days with IntelliCap CR capsule intake, and fecal sample collection. Participants will not directly benefit from the study. There are minor risks for the participants during the study. The CE certified IntelliCap® CR system, used as minimally invasive sampling device and validated in humans, is safe and well tolerated. If the IntelliCap® CR capsule is not recovered from the feces within 7 days after administration, an abdominal X-ray will be performed to check if the IntelliCap® CR capsule is still within the body. For the quencher, present in the IntelliCap® CR capsule, thorough safety reports have been written, showing that the doses used in the capsule are safe for human application.
Based on these considerations, to our opinion, the risks for participation in this study are negligible, and we have made every effort to minimize potential risks. Therefore, we feel that the remaining risks are acceptable and do not outweigh the scientific relevance of this study.

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. Male
2. Age 18-30yrs
3. BMI between 18,5-25 kg/m2
4. Healthy as assessed by the NIZO lifestyle and health questionnaire (*Verklaring leefgewoonten en gezondheid*).
5. Non-smoking
6. Regular bowel movement (defecation on average once a day, at least 4 times/week).
7. Signed informed consent

Exclusion criteria

1. Alcohol consumption > 15 units/week and > 3/day.
2. Allergic to dairy products (milk allergy or lactose intolerance).
3. Carrying a pacemaker or any other (implanted) medical electronic device.
4. Drug abuse.
5. Having diarrhea within two (2) months prior to the study start.
6. Heavy exercise or sports training > 10 hours/week.
7. History or presence of any clinically important disease or disorder which, in the opinion of the Investigator, may either put the subject at risk because of participation in the study, or influence the results or the subject*s ability to participate in the study.
8. Mental status that is incompatible with the proper conduct of the study.
9. Participation in any scientific study with oral, intravenous or inhalatory administration of any substances during two (2) months before study start.
10. Presence of swallowing disorder or problems with gastro-intestinal transit.
11. Reported special diets such as vegetarian, vegan, or macrobiotic.
12. Scheduled for an MRI scan during the study period.
13. Unstable body weight (weight gain or loss >5kg in the past three (3) months).
14. Use of antibiotics during the six (6) months prior to study start.
15. Use of any prescribed or non-prescribed medication (other than paracetamol) during the three (3) weeks prior to study start.
16. Use of laxatives and probiotic, prebiotic and fiber supplements during the two (2) months prior to study start.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2017
Enrollment:	6
Type:	Anticipated

Medical products/devices used

Generic name:	IntelliCap® CR system
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	14-03-2017
Application type:	First submission
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	NL59320.081.16