Study of the effect of Lactobacillus LB product on healthy volunteers' fecal microbiota composition

Published: 14-03-2019
Last updated: 09-04-2024

To explore the effect of 5 weeks daily consumption of Lactobacillus LB product, compared to a placebo supplement, on fecal microbiota composition and diversity in healthy individuals.

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

Summary

ID

NL-OMON48365

Source
ToetsingOnline

Brief title
SOLVE

Condition

- Other condition

Synonym
intestinal flora, Microbiota

Health condition

healthy gut physiology/microbiome

Research involving
Human

Sponsors and support

Primary sponsor: NIZO food research
Source(s) of monetary or material Support: Adare Pharmaceuticals Inc.

Intervention

Keyword: Gut microbiota, Lactobacillus LB product

Outcome measures

Primary outcome

Change in fecal microbiota composition and fecal microbiota diversity as

assessed by 16S rDNA Illumina (MiSeq) sequencing.

Secondary outcome

Change in plasma CRP concentration in fasting blood samples

Study description

Background summary

This research project aims to characterize the effects of Lactobacillus LB product (a lyophilized, heat-killed Lactobacillus LB with its spent culture supernatant) on gut bacterial composition in healthy subjects, to find additional explanations how Lactobacillus LB product may be effective in treating several gastrointestinal infectious diseases.

Study objective

To explore the effect of 5 weeks daily consumption of Lactobacillus LB product, compared to a placebo supplement, on fecal microbiota composition and diversity in healthy individuals.

Study design

Randomised, double-blind, placebo-controlled cross-over trial. After a 1-week run-in period, subjects will be randomised and assigned to a treatment order. Treatment periods have a duration of 5 weeks, with a wash-out period of 2 weeks in between.

Intervention

Lactobacillus LB product and placebo will be provided to the subjects as capsules. Subjects will receive 4 capsules per day divided into two servings (2x2) for 5 weeks. Capsules contain 170 mg of Lactobacillus LB product (containing 10 billion heat-killed bacteria bodies (kbb)) or sucrose.

Study burden and risks

For this study healthy volunteers are selected. There is no direct benefit from participation and volunteers will be reimbursed for their time investment. In total the subjects will visit the clinical facilities 5 times. There are no known risks associated with the consumption of the IP or placebo. Blood samples will be taken 4 times during the study and 4 times a spot fecal sample has to be collected at home by the subject. The risk and burden associated with participation in this study is considered minimal.

Contacts

Public
NIZO food research

Kernhemseweg 2
Ede 6718ZB
NL
Scientific
NIZO food research

Kernhemseweg 2
Ede 6718ZB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:;Substantial
1. Age *18 and *65 years.
2. BMI *18.5 and *30.0 kg/m2.
3. Healthy as assessed by the NIZO health questionnaire.;Procedural:
4. Ability to follow Dutch verbal and written instructions.
5. Availability of internet connection.
6. Signed informed consent.
7. Willing to accept disclosure of the financial benefit of participation in the study to the authorities concerned.
8. Willing to accept use of all encoded data, including publication, and the confidential use and storage of all data for at least 15 years.
9. Willing to comply with study procedures and guidelines, including collection of stool and blood samples.
10. Willingness to abstain from (products containing) probiotics and prebiotics starting from run-in and during the entire study.
11. Willingness to give up blood donation starting at run-in and during the entire study.
12. Willing to take precautions not to become pregnant during the study period.
13. Willingness to avoid use of dietary fiber supplements along the duration of the study

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:;Substantial:
1. Acute gastroenteritis in the 2 months prior to inclusion.
2. Known history or presence of clinically significant neurologic, hematologic, endocrine, oncologic, pulmonary, immunologic, genitourinary, gastrointestinal, psychiatric, or cardiovascular disease or any other condition which, in the opinion of the Investigator, would jeopardize the safety of the subject or impact the validity of the study results.
3. Any active infections, potentially requiring antibiotic use, at time of screening
4. Excessive alcohol usage (men: >4 consumptions/day or >20 consumptions/week; women: >3 consumptions/day or >15 consumptions/week) or drug (ab)use, and not willing/able to stop this during the study.
5. Reported average stool frequency of >3 per day or <1 per 2 days.
6. 6. Having used Lactobacillus LB product/s or (products containing) added pro- and/or prebiotics within 2 weeks prior to inclusion.
7. Use of antibiotics or regular use of norit or laxatives (in 6 months prior to inclusion)
8. Reported special diets such as vegetarian, vegan, or macrobiotic.

9. A self-reported lactose intolerance.
10. Pregnancy or lactating;Procedural:
11. Not having a general practitioner, not allowing disclosure of participation to the general practitioner or not allow to inform the general practitioner about abnormal results.
12. 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.
13. Personnel of NIZO food research and Adare Pharmaceuticals and their partner and their first and second degree relatives

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-05-2019
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	14-03-2019
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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	NL68859.072.19

Study results

Date completed:	06-08-2019
Actual enrolment:	30