The effects of oral administration of lactobacillus plantarum WCFS1, Lactobacillus plantarum CIP104448, and Lactobacillus plantarum CIP104450 on small intestinal mucosa and barrier function

Published: 25-07-2011
Last updated: 27-04-2024

This research aims to investigate the effects of three bacteria in the small intestine. This study will provide detailed information on all processes in the small intestine. By the used analytical technique, including gene expression technology, not...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON35954

Source
ToetsingOnline

Brief title
oral probiotics

Condition

- Gastrointestinal inflammatory conditions

Synonym
gastrointestinal discomfort, irritable bowel syndrome

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Top Institute for Food and Nutrition

Intervention

Keyword: immune, permeability, probiotics, small intestine

Outcome measures

Primary outcome

1. Effects on immune modulation. Measurement of IL-10 and IL-12 production

2. Effect on intestinal epithelial permeability.

Secondary outcome

1. Effects on epithelial gene regulation, tight junction modulation

2. Effects on peripheral markers of immune regulation, immune parameters

Study description

Background summary

The intestine harbours large amounts of bacteria which are essential for the proper functioning of the digestive system. They are among others involved in the degradation of nutrients and the body's immune system. Little is known about the exact health benefits of providing additional 'good ' bacteria in the small intestine. This is mainly due to the small intestine are difficult to study, by its poorly accessible position in the body.
In this study we will examine effects of three food bacteria.

Study objective

This research aims to investigate the effects of three bacteria in the small intestine. This study will provide detailed information on all processes in the small intestine. By the used analytical technique, including gene expression technology, not only information about 'likely' processes is obtained, but also about all other processes. Furthermore, information of putative probiotics on functional parameters of gut health is obtained.

Study design

The study consists of four different periods. During each period, the effects of one of the three bacteria or placebo, an inactive substance, will be investigated. Each participant will go through all four time periods according to the randomized double-blind placebo-controlled cross-over design of this study.
Before starting a test period, a sugar test that provides insights into the barrier function of the intestine will be performed.Two days later, this test is repeated, with concomitant administration of indomethacin. These permeability assessments serve to obtain baseline values of intestinal permeability.
The day after this second sugar test, the participant begins to take the bacteria. The bacteria are provided in small jars. They're in a dry form in those jars. He / she also gets a jar of sugar. Fifteen minutes before consumption, the jar needs to be filled with water, as shown and instructed during the first visit to the investigator. Then drink the 'probiotic' drinks within one minute. The supplements will need to be taken during breakfast and dinner for a 7-days period. After this 7-day period, Intestinal permeability will be assessed again with the 'indomethacin' protocol. If he / she appears as agreed at the hospital, a sugar test will first be carried out, followed by a bowel examination. During this procedure, samples from the duodenal mucosa are obtained by standard flexible gastroduodenoscopy.
Before and after each test week, a blood sample will be collected. Also, subjects will have to fill in a questionnaires which relates to bowel habits. Another bowel symptom questionnaire will have to be completed on the evening of each day.

There will be a wash-out period of 4 weeks in between two experiments.

Intervention

Food supplements (probiotics) for 4 periods of 1 week each, sugar tests with subsequent urine collection, gastroduodenoscopy (intestinal investigation)

Study burden and risks

Bruise by blood sampling
The chance of complications during gastroduodenoscopy, such as a mild bleeding at the site of the biopsy, is about 0.13%, including a 0.03% chance of perforation.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

Postbus 5800
6202 AZ Maastricht
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

Postbus 5800
6202 AZ Maastricht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

no gastrointestinal complaints
age between 18 and 65 yrs
BMI between 20 and 30 kg/m2

Exclusion criteria

medication, except oral contraceptives
major abdominal surgery interfering with gastrointestinal function in the 180 days prior to study
smoking

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-10-2011
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	25-07-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL35728.068.11