The effects of the synbiotic Ecologic 825/scFOS on intestinal barrier function and immune modulation

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

Summary

ID

NL-OMON38875

Source
ToetsingOnline

Brief title
Effects of synbioticum on intestinal barrier function

Condition

- Gastrointestinal infections

Synonym
gastrointestinal symptoms

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Food and Nutrition Delta (FND) subsidie

Intervention

Keyword: barrier function, immune system, probiotics, synbiotics

Outcome measures

Primary outcome

• Sugar recovery in urine, as indicator of intestinal permeability

Secondary outcome

- Measurements in blood at baseline and after the supplementation period

• Biomarkers of immune modulation; plasma levels of TNFa, IL-1b, IL-6, IL-8,

IL-17, MCP-1 and MIP-1a

- Measurements in small intestinal fluid (duodenum/jejunum/ileum) and feces

• Relative abundance of CRIB

• Microbial diversity and population dynamics

• In situ gene expression of the microbiota

- Questionnaire at baseline, during and after the supplementation period

• The symptom diary

Study description

Background summary

The intestine contain large amounts of bacteria that are essential for proper functioning of the digestive system. They are involved in the breakdown of nutrients, and in the immune system of the body. Little is known about the exact health effects of supplementation of "good" bacteria, also called probiotics. Research has shown that supplementation of probiotics in the presence of prebiotics, a so-called synbiotic supplement, may have more pronounced beneficial effects on human health than supplementation of pro- or prebiotics alone. In this study, we will determine the effects of a new synbioticum on the bacterial composition of intestinal fluid and feces. We will also examine the effects of the synbioticum on intestinal barrier function and

the immune system of the body.

Study objective

The primary objective of this study is to assess the effects of the symbiotic Ecologic 825/scFOS on intestinal epithelial permeability.

This study has five secondary objectives:
1. The first secondary objective of this study is to study the microbiota composition in healthy humans at three different points along the small intestinal tract (duodenum, jejunum, ileum) using culture-independent approaches.
2. The second secondary objective of this study is to assess the impact of supplementation of the synbiotic Ecologic® 825/scFOS on the population dynamics and functionality of the microbiota along the gastrointestinal tract (duodenum, jejunum, ileum and feces) using culture-independent approaches. This includes potential stimulation of CRIB, as determined by 16S rRNA gene copies counts in ileum fluid.
3. The third secondary objective of this study is to assess the effects of the synbiotic Ecologic® 825/scFOS on immune modulation, by determining the levels of several cytokines and chemokines in blood plasma (TNFa, IL-1b, IL-6, IL-8, IL-17, MCP-1 and MIP-1a).
4. The fourth secondary objective of this study is to determine whether ileal CRIB counts associate with any of the parameters mentioned under the primary objective, and under the third secondary objective.

Study design

During a 17-days period, all patients will consume supplements containing either 1) probiotics (mix of several species called Ecologic 825) and scFOS/supplement ; 2) placebo during breakfast and during dinner. Prior to the start of the supplementation period, several baseline measurements will be done. First, the microbial composition of the intestinal fluid in the proximal-mid- and distal small intestine will be determined. To enable this, a naso-ileal sampling catheter will be placed with the catheter tip located in the ileum . After successful positioning of the catheter, 10 ml of intestinal fluid will be sampled from each location by aspiration using a 20-ml syringe. After sampling, the catheter will be removed by gently retracting the catheter. On the same day, a blood sample will be obtained to measure parameters of the immune system , and a fecal donation will be handed in by the subject, to determine the effects of the intervention on microbial composition of feces. On the next morning, small intestinal permeability will be assessed non-invasively. Two days after this first permeability assessment, intestinal permeability in a stressed condition will be determined using an indomethacin challenge. The indomethacin challenge will compromise the gut. These two subsequent measurements of intestinal permeability serve to obtain baseline

permeability values as references for the intervention values. After a 14-days supplementation period, this whole procedure will be performed for a second time conform protocol prior to intervention: (positioning of a naso-ileal sampling catheter, sampling of small intestinal fluid on the next day together with collection of blood and fecal samples, followed by a permeability test the next morning and a last permeability test under stressed conditions two days later.
Gastrointestinal symptoms and feelings of well-being will be scored every second day prior to sleeping, by completing the symptom diary.

Intervention

Positioning of a feeding catheter, to be applied for fluid sampling from the small intestine.
Blood sampling.
Sugar test (consumption of sugar drink and collection of urine) for the assewssment of intestinal barrier function.
Collection of feces.

Study burden and risks

During feeding catheter positioning, subjects will suffer from local discomfort in the throat.
After positioning of the feeding catheter, tits exact location will be checked using fluoroscopy. The radiation exposure is very small (total radiation exposure during this study will maximally be 0.2 mSv effective dose), and will not induce risks for these healthy volunteers.
A subject will spend 12.5 hrs in total to the participation in this study, over a total study duration of 21 days.

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

no gastrointestinal complaints
age between 18 and 65 yrs
BMI between 20 and 30 kg/m^2

Exclusion criteria

Use of medication within 14 days prior to testing
Administration of probiotics, investigational drugs, or participation in a scientific intervention study in the 180 days prior to testing
Use of antibiotics in the 90 days prior to testing
women; pregnancy

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):	20-11-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	26-08-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-11-2013
Application type:	Amendment
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	NL43972.068.13