Pilot study on immune modulatory activity of a pre-probiotic blend in healthy adult volunteers

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The objective of this study is to investigate the systemic immunoregulatory effect of synbitoics intervention after 8 weeks of daily study product intake

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

Summary

ID

NL-OMON45397

Source
ToetsingOnline

Brief title
SYNTREG

Condition

- Allergic conditions

Synonym
food allergy

Research involving
Human

Sponsors and support

Primary sponsor: Nutricia Research
Source(s) of monetary or material Support: Nutricia Research

Intervention

Keyword: healthy adults, immune system, prebiotics, probiotics

Outcome measures

Primary outcome

Change from baseline in IL-10 production and/or forkhead box protein 3 (Foxp3) expressing cells after 8 weeks of daily study product intake.

Secondary outcome

- Change from baseline in IL-10 production and/or Foxp3 expressing cells after 2 weeks of daily study product intake

- Change from baseline in the levels of several cytokines and prostaglandin E2 (PGE2) and fatty acid composition after 2 and 8 weeks of daily study product intake

- Adverse events (AEs), gastrointestinal (GI) tolerance, stool frequency, consistency and colour.

Study description

Background summary

Food allergies affect up to 3% of the population of infants and young children in western countries. For these children hypoallergenic infant formula is available on the market. Hypoallergenic food decreases the chance of allergic reactions. Nutricia Research is now developing a new version of this infant formula containing synbiotics. These synbiotics may affect the composition of bacteria in the intestines of children with allergies in such a way that it more resembles that of children without allergies. This could decrease the chance of having an allergic reaction. The effect of this new version of the hypoallergic infant formula in infants and children with cow's milk allergy is currently being investigated in 2 other studies. The goal of this study is to learn more about the possible effects of synbiotics on the immune system. Because this study is hard to execute in children for several reasons, it will

be executed in healthy adult volunteers.

Study objective

The objective of this study is to investigate the systemic immunoregulatory effect of synbitoics intervention after 8 weeks of daily study product intake

Study design

This is a randomised, double-blind, parallel-group, placebo-controlled, single-centre, 8 week multiple-dose study in 30 healthy adult volunteers.

Intervention

Test product: A pre-probiotic blend and maltodextrose
Control product: maltodextrose

Study burden and risks

Subjects will visit the research unit for a screening- and 3 study visits over a period of 8 weeks. During the visits, blood and saliva will be collected and subjects have to collect stool samples at home and hand in during the visits. Subjects should take the study product daily for 8 weeks and should complete questionnaires regularly. During participation, the subjects have to comply with a number of rules related to the use of medication and supplements, sport, food, alcohol and drugs.

There are no known risks of the study products, however the product may alter the stool colour, consistency and frequency in the first days/ weeks of use, and may cause stomach cramps, diarrhea and flatulence which may cause some temporary pain or discomfort.

A light pain can be experienced in the arm during the placement of the needle for blood sampling. Sometimes a blue spot appears afterwards at the place of sampling.

Since the study will be performed with food ingredients, no serious adverse events are expected. The amounts of pro- and pre-biotics in the study product fall within the GRAS status (generally recognized as safe).

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

- Age * 18 and * 40 years
- Written informed consent
- Willingness and ability to comply with the study protocol
- Body Mass Index (BMI) * 18.5 and * 24.9 kg/m2
- Non-smoking or stopped smoking for at least 3 months prior to Visit 1 (randomisation)
- Regular stool (stool frequency of at least 1 stool in 3 days)
- Judged by the investigator to be in good health

Exclusion criteria

- Any medical condition that interferes with GI function (e.g irritable bowel syndrome, short bowel syndrome, inflammatory bowel disease, gastric ulcer, gastritis (gastro)enteritis)
- Constipation and/or diarrhoea within 1 week prior to Visit 1 (randomisation)
- Any known allergy and/or intolerance (e.g. coeliac disease, gluten intolerance, allergy to one of the ingredients of the study product)
- Any known renal or hepatic failure
- (History of) any immunological disease and/ or immunodeficiency

- (History of) any cancer with the exception of basal cell carcinoma
- Use of prokinetics, laxatives, antidiarrhoeals, corticosteroids, proton-pump inhibitors (or other gastric acid reducers), immunosuppressants or any active allergy treatment within 3 weeks of Visit 1 (randomisation)
- (History of) any chemotherapy or immunotherapy
- Use of antibiotics within 3 months of screening

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-03-2017
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	17-10-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-01-2017
Application type:	Amendment

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	NL58758.056.16