A study proposal to investigate the sequels of mucosal inflammation caused by ETEC infection- the effects of probiotics

Published: 20-10-2010
Last updated: 04-05-2024

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

Summary

ID

NL-OMON34387

Source
ToetsingOnline

Brief title
intestinal barrier function and probiotics

Condition

- Other condition
- Gastrointestinal infections
- Immune disorders NEC

Synonym
traveler's diarrhoea

Health condition

Populatie van bacterien in de darm en algemene gezondheid en "innate immunity"

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: Ministerie van OC&W,VSL Pharmaceuticals Inc., Roma

Intervention

Keyword: Intestinal inflammation, Probiotics

Outcome measures

Primary outcome

The main study parameter is the percent change in faecal dry weight and total

faecal output between the probiotics group and the placebo group

Secondary outcome

In addition, intestinal permeability, inflammation and other clinical symptoms

will be evaluated.

Study description

Background summary

Enterotoxigenic Escherichia coli (ETEC) bacteria adhere to the mucosa of the proximal intestines and an infection is therefore a local and relevant challenge for the intestines, giving an indication of general resistance and/or the local resistance of the intestines. We will evaluate the effects of probiotics by comparing the infection symptoms and by measuring faecal weight and mucus in faeces. The sequel of events of mucosal inflammation will be characterized in this study and biomarkers for these sequels will be evaluated

Study objective

The main objective of this study is to investigate the effect of probiotics on the sequels of ETEC administration as intestinal permeability, inflammation and clinical signs as total faecal output, relative faecal dry weight and mucin

excretion in faeces. In addition biomarkers for intestinal health and onflammation will be evaluated.

Study design

The study is designed as a randomized, parallel, placebo-controlled, double-blind study. Study substance (probiotics) and placebo will be given during 4 weeks.

Intervention

One group receives twice daily two sachets containing 450 billion live freeze-dried lactic acid bacteria per sachet and the other group receives twice daily a two placebo sachets. On day 21 all volunteers will be infected with an attenuated ETEC strain to induce mild traveler's diarrhoea.

Study burden and risks

In this study healthy male volunteers will be challenged with an attenuated ETEC strain after three week of either probiotics or placebo. This infection will lead to a mild traveller*s diarrhoea in the subjects during approximately three days maximally. Sequels of this infection and the effects of commercially available probiotics compared to placebo will be followed up. The subjects will therefore collect their faeces on several days, record their defecation pattern and gastro-intestinal complaints during four weeks, undergo a physical examination and five venapunctions, and visit our facilities in total on 8 days (excluding two pre-study visits). The oral administration of probiotics in a healthy population is not associated with risk

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. Healthy as assessed by the
- health and lifestyle questionnaire, (P9067 F02; in Dutch)
- physical examination
- results of the pre-study laboratory tests
2. Males, Age 21 - 40 years at Day 01 of the study
3 Body Mass Index (BMI) >20 and < 33 kg/m2. Preferably in high and low body fat mass ranges as to be determined by waist circumference
4 Normal Dutch eating habits as assessed by P9067 F02
5 Voluntary participation
6 Having given written informed consent
7 Willing to comply with the study procedures, including the ETEC challenge
8 Willing to accept use of all nameless data, including publication, and the confidential use and storage of all data for at least 15 years
9 Willing to accept the disclosure of the financial benefit of participation in the study to the authorities concerned.

Exclusion criteria

Subjects with one or more of the following characteristics will be excluded from participation:
1. Participation in any clinical trial including blood sampling and/or administration of substances up to 90 days before Day 01 of this study
2. Participation in any non-invasive clinical trial up to 30 days before Day 01 of this study, including no blood sampling and/or oral, intravenous, inhalatory administration of substances
3. Having a history of medical or surgical events that may significantly affect the study outcome, including gastrointestinal illness or surgical operations,
4. Use of antibiotics, immunosuppressive drugs, antacids, laxatives or antidiarrheal drugs in the last 3 months before the study

5. Alcohol consumption > 28 units/week for males .
6. Reported unexplained weight loss or gain of > 2 kg in the month prior to the pre-study screening
7. Reported slimming or medically prescribed diet
8. Reported vegan, vegetarian or macrobiotic
9. Working as a food handler, in child care or as a healthcare worker with direct patient contact
10. Not willing to give up blood donation during the study.
11. Personnel of TNO Quality of Life, their partner and their first and second degree relatives
12. Not having a general practitioner
13. Not willing to accept information-transfer concerning participation in the study, or information regarding his/her health, like laboratory results, findings at anamnesis or physical examination and eventual adverse events to and from his general practitioner.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-11-2010
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO

Date:	20-10-2010
Application type:	First submission

Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	12-01-2011
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL33744.028.10