Lactobacillus casei Shirota for influencing the microbiome in Barrett's esophagus

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25973

Source
NTR

Brief title
The Yakult study

Health condition

Barrett's Esophagus

Sponsors and support

Primary sponsor: Radboud University Medical Center
Source(s) of monetary or material Support: Yakult Nederland B.V. Handelsweg 59H 1181 ZA Amstelveen The Netherlands

Intervention

Outcome measures

Primary outcome

The ability of LcS to colonize the esophagus and if so, if we can see a shift in the Gr+(with and without LcS)/Gr- bacterial ratio to a more predominantly Gr+ microbiome.

Secondary outcome

- The number of specific pathogenic bacteria, i.e; Campylobacter spp, Veilonella spp, Neisseria spp. Fusobacterium spp and Prevotella spp.

- To explore the effect of restoration of the Gr+/Gr- on the local immunological response, i.e. IL-10, IL-18 and TGF-â.

Study description

Background summary

The aim of this study is to evaluate if LcS is capable of influencing the microbiome and thereby altering the inflammatory reaction in BE.

Study design: Pilot study, not randomized.

Study population: 20 Patients with BE without (prior) dysplasia, age ≥ 18 years.

Intervention: Patients will be drinking 2 bottles per day of a LcS containing drink (Yakult), for a period of 4 weeks.

Study objective

LcS is able to colonize the esophagus.

Study design

4 weeks

Intervention

Yakult is a fermented milk drink containing at least 6,5*10^9 Lactobacillus casei Shirota. The other ingredients are Water, Syrup (Glucose fructose syrup, sugar, Maltodextrin), Skimmed milk powder and flavouring. Yakult is gluten free.

Contacts

Public
Department of Gastroenterology and Hepatology (455)

Yonne Peters
P.O. box 9101

Nijmegen 6500 HB
The Netherlands
+31615956464
Scientific
Department of Gastroenterology and Hepatology (455)

Yonne Peters
P.O. box 9101

Nijmegen 6500 HB
The Netherlands
+31615956464

Eligibility criteria

Inclusion criteria

- Age ≥ 18 years

- Histopathological proof of BE without dysplasia

- BE length of >2 cm (CxM2)

- Signed informed consent

Exclusion criteria

- Probiotic use within the last 3 months before baseline

- Antibiotic use within the last 2 months before baseline

- Infection of the oral cavity

- Esophagitis according to the Los Angeles classification (gr. A-D)

- Patients with H. Pylori infection

- Immunocompromised patients; HIV-infection, systemic immunosuppression therapy

- Patients with diabetes mellitus

- Patients with a vegetarion or gluten-free diet

- Patients with lactose intolerance

- Previous gastric/esophageal surgery, which has changed esophageal anatomy.

- Other coexistent esophageal diseases (e.g. varices)

- Patients with bleeding disorders

- Other situations that contraindicate gastroscopy, e.g. anti-coagulants (monotherapy aspirin can be continued safely), the inability of the patients to cooperate with the procedure despite adequate attempts at sedation.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2017
Enrollment:	20
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	28-12-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43164
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6620
NTR-old	NTR6950
CCMO	NL59072.091.16
OMON	NL-OMON43164

Study results