

Are probiotics beneficial for ulcerative colitis patients with poor pelvic pouch function?

Submission date 19/01/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/02/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/02/2009	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Effect of probiotics (Lactobacillus plantarum 299® plus Bifidobacterium Cure 21®) or placebo on the pouch bacterial flora and immunological response patterns in poor pelvic pouch function: a randomised controlled trial

Study objectives

The bacterial flora and immunological response patterns in pelvic pouches will be modified by supplemental probiotics. This could stabilise/improve pouch function (frequency of bowel movements, urgency, leakage etc.).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local Ethics Committee at Gothenburg University, approved on 01/12/2003 (ref: O 644-03)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Ulcerative colitis

Interventions

Participants are randomly allocated to the following two arms (randomisation ratio 1:1).

Intervention group: Probiotics (Lactobacillus plantarum 299® [5 x 10⁹ cfu] plus Bifidobacterium Cure 21® [5 x 10⁹ cfu]) administered orally (p.o.), twice a day for 3 weeks
Control group: Placebo (p.o.) twice a day for 3 weeks

The final clinical and laboratory examination is carried out at the end of treatment (at 3 weeks). A further evaluation will be carried out by a questionnaire 3 weeks after the end of treatment.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Lactobacillus plantarum 299®, Bifidobacterium Cure 21®

Primary outcome measure

The following will be assessed at baseline and end of treatment (3 weeks):

1. Types of bacterial species in the pelvic pouch, analysed by non-culture dependent techniques, such as Terminal-Restriction Fragment Length Polymorphism (T-RFLP)
2. Markers of mucosal inflammation in faeces: calprotectin, lactoferrin, myeloperoxidase (MPO) and eosinophil cationic protein (ECP)
3. Inflammation of the lining of the rectum and colon, assessed by biopsies
4. Immunological response patterns, assessed by examination of leukocytes in blood samples

Secondary outcome measures

1. Clinical pouch function is evaluated by a questionnaire before and within 3 days from the end of treatment
2. Pouch biopsies are evaluated by standard histopathology before and within 3 days from the end of treatment

Overall study start date

01/01/2006

Completion date

31/05/2009

Eligibility**Key inclusion criteria**

1. Both males and females, age 18-75 years
2. Patient with a pelvic pouch because of ulcerative colitis. The pouch function should be inferior according to a clinical evaluation including a pouch function score.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

Both

Target number of participants

30

Key exclusion criteria

1. Patient with a pelvic pouch, but with other diagnoses, e.g., Crohn's disease or polyposis
2. Patients with good pouch function

Date of first enrolment

01/01/2006

Date of final enrolment

31/05/2009

Locations**Countries of recruitment**

Sweden

Study participating centre

Östra Sjukhuset

Gothenburg

Sweden

SE 41685

Sponsor information**Organisation**

Probi AB (Sweden)

Sponsor details

Ideon Gamma 1

Sölvegatan 41

Lund

Sweden

SE - 223 70

probi@probi.se

Sponsor type

Industry

Website

<http://www.probi.com/>

ROR

<https://ror.org/03yf63872>

Funder(s)

Funder type

University/education

Funder Name

Main funding:

Funder Name

Gothenburg University (Sweden)

Funder Name

Supplementary funding:

Funder Name

Björnson Foundation (Sweden) (Research grant)

Funder Name

Ihre Foundation (Sweden) (Research grant)

Funder Name

Probi AB (Sweden)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration