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

Submission date 19/01/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 16/02/2009	**Overall study status** Completed	
Last Edited 16/02/2009	**Condition category** Digestive System	

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 10^9 cfu] plus Bifidobacterium Cure 21® [5 x 10^9 cfu]) administrated 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