ISRCTN45167712 https://doi.org/10.1186/ISRCTN45167712

The effect of oral administration of a multispecies probiotic product in healthy volunteers and ileostomy patients; double-blind, placebo-controlled, cross-over trial

Submission date
28/06/2005

Recruitment status
No longer recruiting

Registration date
12/09/2005

Overall study status
Completed

Last Edited
14/09/2009

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

04-088

Study information

Scientific Title

Study objectives
Ecologic 641 (a multispecies probiotic) is well tolerated and is capable of modifying gut flora.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Healthy volunteers and ileostomy patients after ulcerative colitis

Interventions
Administration of probiotics or placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Ecologic 641 (a multispecies probiotic)

Primary outcome measure
Tolerance of study product and gut flora modification

Secondary outcome measures
Side effects, discomfort scores (visual analogue scale [VAS] scale)

Overall study start date
01/08/2004

Completion date
01/07/2005

Eligibility

Key inclusion criteria
10 healthy volunteers and 10 ileostomy patients after ulcerative colitis

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
Use of antibiotics and/or probiotics within 2 weeks prior to randomisation

Date of first enrolment
01/08/2004

Date of final enrolment
01/07/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
Heidelberglaan 100
Utrecht
Netherlands
3584 CX

Sponsor information

Organisation
Individual Sponsor (Netherlands)

Sponsor details
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Sponsor type
Not defined

Website
http://www.prosearch.nl

Funder(s)

Funder type
Government

Funder Name
Senter, an agency of the Dutch Ministry of Economic Affairs, funded this study (grant number: TSGE3109) (Netherlands)

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