

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	☐ Prospectively registered
		☐ Protocol
Registration date 12/09/2005	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 14/09/2009	Condition category Digestive System	☐ 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

Protocol serial number

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

Study type(s)

Not Specified

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(s)

Tolerance of study product and gut flora modification

Key secondary outcome(s))

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

Completion date

01/07/2005

Eligibility**Key inclusion criteria**

10 healthy volunteers and 10 ileostomy patients after ulcerative colitis

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration