ISRCTN11348435 https://doi.org/10.1186/ISRCTN11348435

A one year, randomised, double blind, placebo controlled trial of probiotics. Bifidobacterium infantis 35624 or Lactobacillus salivarious UCC118, as food supplements for maintenance of remission in Ulcerative colitis.

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/09/2011	Digestive System	[ ] 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
N0176127663

Study information

Scientific Title

Study objectives
The primary aim of the study is to determine whether ingestion of probiotic preparations (containing Lactobacillus salivarious subsp. Salivarious UCC118 or Bifidobacterium infantis 35624) can help in the maintenance of remission of patients with ulcerative colitis over a period of one year (i.e. delay the onset of relapse). Secondary aims include an evaluation of the immunological and biochemical parameters of the immuno-inflammatory response and an assessment of the faecal flora in patients consuming the probiotic and control products.

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
Digestive System: Ulcerative colitis

Interventions
1. Bifidobacterium infantis 35624
2. Lactobacillus salivarious UCC118
3. Placebo

July 2008: no patients enrolled in this trial.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Probiotoc preparations

Primary outcome measure
A failure to maintain remission over a period of 1 year. Using the simple ulcerative colitis activity index, a score of >- 7 indicates relapse. (i.e. Relapse - CAIA >- 7 and/or a requirement for clinical intervention e.g. drugs/surgery etc.)

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/2001

Completion date
31/12/2004

Reason abandoned (if study stopped)
No patient enrolled.

Eligibility

Key inclusion criteria
120 patients, 60 control patients.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
180

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/10/2001

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Gastroenterology Lab
Oxford
United Kingdom
OX2 6HE

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Oxford Radcliffe Hospitals NHS Trust (UK)

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