

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

Submission date 30/09/2004	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/09/2011	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

N0176127663

Study information

Scientific Title

Study objectives

The primary aim of the study is to determine whether ingestion of probiotic preparations (containing *Lactobacillus salivarius* subsp. *Salivarius* 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 salivarius* 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