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Randomised controlled trial of soluble plantain fibre for maintenance of health during periods of remission in Crohn's disease

Submission date 30/10/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 03/01/2007	**Overall study status** Completed	
Last Edited 10/07/2017	**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

Protocol serial number
N/A

Study information

Scientific Title
Randomised controlled trial of soluble plantain fibre for maintenance of health during periods of remission in Crohn's disease

Study objectives
That supplementation of the normal diet with a preparation containing high molecular weight forms of soluble plantain fibre may be effective in maintaining disease-free periods in people diagnosed with Crohn's disease. Laboratory studies using a simulated intestinal microbiota have shown that a substantial proportion of these high molecular weight forms are likely to survive passage through the human intestine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration – submission pending

Study design
Double-blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Crohn's disease

Interventions
Patients will receive either:
1. Soluble plantain fibre
2. Placebo

The supplements will be provided to subjects in individual sachets containing 5 g soluble plantain fibre which represents half the daily dosage. The placebo will be identical to the test supplement in appearance, volume and taste but will contain additional maltodextrin instead of soluble plantain fibre.

Patients will be required to consume two sachets per day. Supplies will be prescribed at three monthly intervals for 12 months.

Intervention Type
Supplement

Primary outcome(s)
Relapse of Crohn's disease, defined as an increase in CDAI more than 100 above baseline or the initiation of corticosteroids or an anti-metabolite (azathioprine, 6-mercaptopurine or methotrexate), or infliximab or any of these in combination for the treatment of symptoms of Crohn's disease.

Key secondary outcome(s))
1. Time to first relapse (days)
2. Relapse, defined as a rise in CDAI more than 150
3. Rise in serum C-Reactive Protein (CRP) concentration of 10 g/l above baseline

4. Deterioration in quality of life score, as measured by disease-specific Health Related Quality of Life (HRQoL) instrument (the UK version of the Inflammatory Bowel Disease Questionnaire) and by a multi-attribute generic measure of utility (EuroQol [EQ5D] questionnaire)
5. Deterioration in patient's global assessment of disease activity as determined by visual analogue scores
6. The need for hospitalisation and/or surgery
7. The direct medical costs from the perspective of the UK National Health Service (NHS)
8. Acceptability of supplement in terms of palatability as determined by visual-analogue scores
9. Impact on faecal constituents, to include measuring transient or permanent alterations in bacterial populations, changes in short chain fatty acid production, and changes in faecal water toxicity

Completion date
15/07/2008

Eligibility

Key inclusion criteria
1. Patients with Crohn's disease as diagnosed by conventional clinical, radiological and histological criteria
2. Crohn's disease involving small bowel, colon or both
3. Crohn's disease that is in remission: Crohn's Disease Activity Index (CDAI) less than 150
4. Patients who have had a relapse of disease within the previous 12 months (Harvey Bradshaw Index modified for retrospective use more than four)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients under 16 or unable to give informed consent
2. Patients who have had surgery for Crohn's disease within the previous 12 months
3. Any change to medication for Crohn's disease within the previous three months
4. Patients receiving corticosteroids or infliximab within the previous three months
5. CDAI more than 150
6. Patients currently receiving enteral nutrition as part of their treatment for Crohn's disease
7. Participation in other trials in the last three months

Date of first enrolment
15/01/2007

Date of final enrolment

15/07/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Liverpool
Liverpool
United Kingdom
L69 3BX

Sponsor information

Organisation
Provexis plc (UK)

ROR
https://ror.org/046pkq184

Funder(s)

Funder type
Industry

Funder Name
Provexis plc (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration