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

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

**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**
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

### 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 measure
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.

### Secondary outcome measures
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

### Overall study start date
15/01/2007

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
64

### 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
England

United Kingdom

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

## Sponsor information

### Organisation
Provexis plc (UK)

### Sponsor details
20 Mortlake High Street
London
United Kingdom
SW14 8JN

**Sponsor type**
Industry

**Website**
http://www.provexis.com/

**ROR**
https://ror.org/046pkq184

# Funder(s)

**Funder type**
Industry

**Funder Name**
Provexis plc (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