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

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

**Prof Jonathan Rhodes** 

#### Contact details

Department of Medicine University of Liverpool Liverpool United Kingdom L69 3BX

# 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

# 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

# **Study outputs**

Output type

Details

Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 No

Yes