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A randomised, double-blind comparison of the microbiological, immunological and clinical effects of a high fructooligosaccharide diet compared with standard diet in patients with moderately active Crohn's disease

Submission date 26/05/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/06/2006	**Overall study status** Completed	
Last Edited 14/09/2011	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr James Lindsay

Contact details
The Royal London Hospital,
Whitechapel
London
United Kingdom
E1 1BB
02073777443
james.lindsay@bartsandthelondon.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Alterations in the balance of the gastrointestinal (GI) microbiota drive the persistent inflammation in Crohns disease. A diet containing high levels of prebiotic carbohydrate such as fructooligosaccharide (FOS) will increase colonic bifidobacteria and induce immunoregulatory dendritic and epithelial cell responses in patients with Crohns disease. This will result in resolution of intestinal inflammation and a reduction in disease activity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Multicentre Research Ethics Committee (MREC) approved 20/04/2006, reference number: 06 /MRE01/32

Study design
Double-blind, controlled trial comparing a high FOS diet with a standard diet in patients with moderately active Crohn's disease

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
Patients will be randomised to either a FOS enriched diet or a control diet for four weeks. Dietary supplements will be used to modify the diet of both the active and control group. Patients will be advised to continue their normal diet throughout the study period. Patients randomised to the high FOS diet will supplement their normal diet with 15 g

BeneoSynergy1 (classified food supplement by the Medicines and Healthcare Products Regulatory Agency [MHRA]) which contains 70% oligo-fructose and 30% inulin.
Patients randomised to the control diet will add 15 g of a non-prebiotic carbohydrate (maltodextrin) to their diet each day. To ensure that the trial is double-blinded, the dietary supplements will be provided in identical packets. Patients will be advised to take three level teaspoons (approx 15 g) each day. This can be used to sweeten hot drinks, dissolved in water or sprinkled on food throughout the course of the day. Patients will be asked to return any unused supplement which will then be weighed to confirm compliance.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary endpoint is clinical response to therapy at week four. Clinical response will be defined as a reduction in the Crohns disease activity index of at least 70 points from baseline.

Secondary outcome measures
1. Disease remission at week four (defined as a reduction in Crohns disease activity index by at least 70 points and to less than 150)
2. Reduction in Harvey Bradshaw index from baseline to week four
3. Clinical response and remission at week twelve
4. Reduction in CRP
5. Improvement in quality of life at week four and twelve as determined by the Inflammatory Bowel Disease Questionnaire (IBDQ)
6. Avoidance of further therapeutic manipulations to control disease activity at week four and twelve
7. Compliance and tolerability of FOS

We will also assess the microbiological and immunological affects of FOS in a subset of patients.

Overall study start date
07/08/2006

Completion date
30/07/2008

Eligibility

Key inclusion criteria
1. The study group will include patients aged 18 years or older with a diagnosis of Crohns disease for at least three months defined by histology or radiology
2. Patients must have moderately active disease as defined by a Crohns disease activity index (CDAI) between 250 and 450 at the baseline visit
3. Only patients with a C-reactive protein (CRP) elevated to above the upper limit of normal of the local laboratory will be included
4. Patients must be on stable Crohns disease therapy with a total steroid dose not exceeding 10 mg prednisolone or equivalent
5. Patients currently taking maintenance oral 5-aminosalicylic acid therapy must have been on a

stable dose for four weeks prior to study entry, and will be maintained at the same dose for the six-week duration of the study
6. No rectally administered medications (steroid or 5-aminosalicylic acid [5ASA]) are allowed for the two weeks preceding baseline and throughout the study
7. Patients on a stable dose of oral steroids (not exceeding 10 mg prednisolone or equivalent) for four weeks prior to baseline are permitted to enter the study, and will remain on that dose throughout the study
8. Patients taking azathioprine or 6-mercaptopurine must have been maintained on a stable dose for at least 16 weeks prior to entry and will continue at that dose throughout the study
9. No antibiotics, probiotics or prebiotics (other than the study prebiotic) will be used during the study or for the preceding month
10. Food frequency questionnaires will be used to assess the consumption of foods that naturally contain prebiotics, although levels within a normal western diet are usually insufficient to affect the composition of the intestinal microbiota
11. Non-steroidal anti-inflammatory drugs (NSAIDs) will not be permitted for one week before and throughout the six-week study period

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
110 patients based upon power calculation

Key exclusion criteria
1. Current infection with an enteric pathogen
2. Use of antibiotics within the last month
3. Consumption of any probiotic within the last month
4. Change in dose of oral steroids within the last four weeks
5. Dose of steroids exceeds 10 mg prednisolone per day or equivalent
6. Change in dose of oral 5-ASA products within the last four weeks
7. Change in dose of azathioprine or methotrexate within the last three months
8. Infusion of infliximab within the last three months
9. Use of any alternative biological therapy within the last three months
10. Use of rectal 5-ASA or steroids within the last two weeks
11. Imminent need for surgery or presence of severe disease (CDAI >450)
12. Patient requiring hospitalization
13. Pregnancy or lactation
14. Short bowel syndrome
15. Pure anal disease and previous proctocolectomy
16. Patients will also be excluded if they have significant hepatic, renal, endocrine, respiratory, neurological or cardiovascular disease as determined by the principal investigator
17. History of cancer with a disease-free state of less than two years

Date of first enrolment
07/08/2006

Date of final enrolment
30/07/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Royal London Hospital,
London
United Kingdom
E1 1BB

Sponsor information

Organisation
Barts and the London NHS Trust

Sponsor details
Joint Research and Development Office, 3rd Floor Rutland House, 42-46 New Road,
London
United Kingdom
E1 2AX

Sponsor type
Not defined

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Charity

Funder Name
Trial Funded by the Broad Medical Research Program - IBD0166R

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2011		Yes	No