ISRCTN17061468 https://doi.org/10.1186/ISRCTN17061468

Dietary Interventions in inflammatory bowel disease (IBD)

Submission date 20/01/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/01/2016	**Overall study status** Completed	
Last Edited 07/10/2019	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Inflammatory bowel disease (IBD) is a term used to describe conditions which cause long-term (chronic) inflammation (swelling) in the digestive tract (gut). The two main forms of IBD are Crohn's disease (CD) and ulcerative colitis (UC). Crohn's disease can affect any part of the gut, but is most common at the end of the ileum (the last part of the small intestine) or the colon (the large intestine). Ulcerative colitis generally affects the colon and rectum (the last part of the large intestine). There is currently no cure for these conditions, and so the main aim of treatment is to reduce the symptoms (remission) and prevent the disease from "flaring up" and becoming active again. Even when the disease is in remission, many patients still experience 'irritable bowel syndrome-like' symptoms, such as bloating, diarrhoea and abdominal (tummy) pain. It can greatly affect their quality of life and so these symptoms need to be well managed. In recent years, the link between diet and irritable bowel syndrome-like symptoms (IBS-like symptoms) has been extensively studied. It is thought that by eating or avoiding certain foods, it is possible improve IBS-like symptoms. The aim of this study is to find out whether a particular diet which involves food restrictions can help to improve IBS-like symptoms, and whether this diet changes the composition of bacteria in the gut in patients with inflammatory bowel disease in remission.

Who can participate?
Adults with inactive IBD who are experiencing 'irritable bowel syndrome-like' symptoms.

What does the study involve?
Patients who meet the initial screening criteria are asked to provide a stool sample and blood sample to measure levels of inflammatory markers. They are then asked to complete a 7-day food and symptom diary. If patients remain eligible based upon the severity of symptoms in this diary, they will be asked to return to the clinic to take part in the main study. These patients go to a clinic appointment which involves completing questionnaires and providing another stool and blood sample. The participants are then randomly allocated to one of two groups. Both groups are given dietary advice however the first group is put on a diet intended to help their IBS-like symptoms and the second group are put on a diet that is not expected to have any

effect on their IBS-like symptoms. Participants are then asked to follow their diets for 4 weeks, keeping a food diary in the final week. All participants then return to the clinic for a follow up appointment, where they hand in their food diaries and provide another stool and blood sample.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement to their IBS-like symptoms as a result of their new diet. There are no specific risks of taking part although some participants may experience pain, discomfort or bruising during blood tests.

Where is the study run from?
Guy’s and St Thomas NHS Foundation Trust and Barts Health NHS Trust (UK)

When is the study starting and how long is it expected to run for?
April 2015 to December 2017

Who is funding the study?
Kenneth Rainin Foundation (USA)

Who is the main contact?
Miss Selina Cox

Contact information

Type(s)
Public

Contact name
Miss Selina Cox

Contact details
King's College London
3.07 Franklin-Wilkins Building
150 Stamford Street
London
United Kingdom
SE1 9NH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20402

Study information

Scientific Title
Dietary interventions for the relief of functional gut symptoms in inflammatory bowel disease

Study objectives
The aim of this study is to find out whether a particular diet which involves food restrictions can help to improve IBS-like symptoms and whether this diet changes the composition of bacteria in the gut in patients with inflammatory bowel disease in remission.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee London – Dulwich, 22/10/2015, ref: 15/LO/1684

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Gastroenterology; Subtopic: Gastroenterology; Disease: All Gastroenterology

Interventions
Participants are randomly allocated to one of two groups who will consume the intervention diet (expected to have an effect on IBS-like symptoms) or sham diet (expected to have no effect on IBS-like symptoms). Both diets will involve restriction of certain foods, e.g. rice, wheat, bananas, cucumber, berries, and appropriate alternative options will be provided so that nutritional adequacy can be maintained. All participants are provided with written information for the diet to which they have been allocated, outlining foods to avoid and those which are permitted during the trial, in addition to supplementary information. Researchers will contact participants weekly to answer any questions or respond to concerns, to monitor compliance to the diet and to document any adverse events.

Intervention Type
Other

Primary outcome measure

Gut symptoms are measured using the Irritable Bowel Syndrome Severity Scoring System score at baseline and 4 weeks.

Secondary outcome measures
1. Gastrointestinal symptoms are measured using the gastrointestinal symptom rating scale at baseline and 4 weeks
2. Stool output (frequency and consistency) is measured using the Bristol Stool Form Scale at baseline and 4 weeks
3. Luminal gastrointestinal microbiota composition, defined as total and individual bacteria and proportions of bacteria, are measured using quantitative polymerase chain reaction and metagenomic sequencingis measured at baseline and 4 weeks
4. Gastrointestinal microbiota metabolites, including SCFA, are measured using gas liquid chromatography at baseline and 4 weeks
5. Peripheral blood mononuclear cell gut homing phenotype, including cell surface homing receptors, measured using multi-colour flow cytometry at baseline and 4 weeks
6. Inflammatory markers, including faecal calprotectin, are measured using ELISA (enzyme linked immunosorbent assay) at baseline and 4 weeks
7. Clinical disease activity is measured using the Harvey-Bradshaw Index (for patients with Crohn' s disease) and the partial Mayo score (for patients with ulcerative colitis) at baseline and 4 weeks
8. Patient reported outcome measures are measured using the IBD-control questionnaire and patient-reported outcome 2 (PRO2) questionnaire at baseline and 4 weeks
9. Health-related quality of life is measured using the inflammatory bowel disease questionnaire and the food-related quality of life questionnaire at baseline and 4 weeks
10. Nutritional intake is measured using 7-day un-weighed food records at baseline and 4 weeks

Overall study start date
01/04/2015

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Diagnosis of IBD confirmed by standard clinical, histological and radiological criteria for least 6 months
3. Inactive disease state (deemed in remission by physician assessment, with GI symptoms that have been assessed with objective investigations and thought not to be a result of active inflammation, and which do not require escalation of IBD
medications)
4. Stable medications (see exclusion criteria), and no GI surgery in preceding 6 months (also see exclusion criteria).
5. Have not experienced an IBD flare-up in past 6 months
6. Faecal calprotectin <250µg/g (screening 2)
7. CRP <10mg/l (blood taken as part of routine out-patient appointment, but results checked during screening 2)
8. Functional symptoms meeting the following Rome III criteria:
8.1. IBS -diarrhoea predominant, or IBS- alternating subtype
8.2. Functional bloating
8.3. Functional diarrhoea

9. Symptoms must also meet the following criteria (screening 2):
9.1. Inadequate relief of gut symptoms at baseline according to the GSQ, assessed on day 7 of screening week
(described previously)
9.2. Presence of mild, moderate or severe abdominal pain, bloating or diarrhoea, assessed using the GSRS, on at least
2 of 7 days of the screening week
10. Have not been exposed to the intervention diet in the past
11. Ability to give informed consent
12. A willingness to participate

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 52; UK Sample Size: 52

Total final enrolment
52

Key exclusion criteria
1. Any evidence of active disease, defined as:
1.1. Requiring a change in treatment as assessed by the treating physician
1.2. Currently taking steroids
1.3. Patients in whom surgery is thought to be imminent
2. Changes in dose to azathioprine, 6-mercaptopurine, methotrexate or anti-TNF-a agents during the preceding 12 weeks, oral 5-ASA during the preceding four weeks.
3. Constipation predominant symptoms (either meeting criteria for IBS-C or functional constipation)
4. Recent use of the following treatments: antibiotics or probiotics (or prebiotics) in the preceding eight weeks, NSAIDs
during the preceding week.
5. Pure perianal disease
6. Current stoma
7. Other factors likely to be cause of gut symptoms:
7.1. Previous extensive colonic resection, or extensive small intestinal resection indicating short bowel syndrome
7.2. Symptoms thought to relate to stenotic disease
7.3. Taking any medications with the potential to influence gastrointestinal symptoms, e.g. lactulose, loperamide, senna (unless taking long-term stable dose that is unlikely to change or stop during the trial)
7.4. Individuals with established bile acid malabsorption

8. Comorbidities:
8.1. Sepsis or fever
8.2. Diabetes or coeliac disease
8.3. Other concomitant serious comorbidity e.g. significant hepatic, renal, endocrine, respiratory, neurological or cardiovascular disease
9. Seen by a dietitian in the preceding 6 months for advice regarding nutrition support
10. Pregnancy or lactation
11. Full bowel preparation for a diagnostic procedure in preceding 4 weeks

Date of first enrolment
22/01/2015

Date of final enrolment
03/07/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Thomas' Hospital
Guy’s and St Thomas NHS Foundation Trust
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
The Royal London Hospital
Barts Health NHS Trust
Whitechapel Road
London
United Kingdom
E1 1BB

Study participating centre
Guy’s hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
King's College London

Sponsor details
Room 1.8
Hodgkin Building
Guy's Campus
London
England
United Kingdom
SE1 4UL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Kenneth Rainin Foundation

Alternative Name(s)
Rainin Foundation, KRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Publication and dissemination plan
The results will be published in peer-reviewed scientific journals, in addition to presentation at relevant conferences.

Intention to publish date
30/06/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2020	07/10/2019	Yes	No
HRA research summary			28/06/2023	No	No