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Dietary interventions in irritable bowel syndrome

Submission date 13/03/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/03/2015	**Overall study status** Completed	
Last Edited 07/04/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Irritable bowel syndrome (IBS) is a digestive disorder that affects up to 15% of the population. Symptoms include stomach pain, bloating and altered bowel habit. It can be very debilitating and has a great impact on the sufferers quality of life. A diet with an altered amount of carbohydrates (e.g. the types of fruits and vegetables) might prevent symptoms such as bloating, stomach pain and flatulence for many people with IBS. Recent research has shown that the diet described above can impact on the amount of bifidobacteria, a group of bacteria that live in the bowel. Prebiotics can promote (increase) the amount of friendly bifidobacteria in the bowel. This study will investigate the effect of this diet with a prebiotic food supplement on:
1. Bacteria in the bowel and the products of bacterial fermentation
2. Gut symptoms (e.g. wind, bloating)
3. Stool frequency and consistency
4. Changes to urine health markers in relation to the gut bacteria changes
5. Dietary intake
6. Quality of life

Who can participate?
Patients of Guy's and St Thomas' NHS Foundation Trust or Barts and the London NHS Trust aged 18-65 years with IBS and without another major medical condition are eligible for this study

What does the study involve?
Participants are randomly allocated into one of three groups. Those in group 1 are placed on a “sham” diet (one that is not expected to make a difference to the persons IBS symptoms) and are given a placebo pill to take for 4 weeks. Those in group 2 are placed on the treatment diet for 4 weeks and are given a placebo. Those in group 3 are also placed on the treatment diet and take the probiotic for 4 weeks. Each participant visits their study centre three times, once before the study begins, once at one week into the study period and once after the study ends. Participants are assessed according to, for example, what symptoms they experience, their nutrient uptake, quality of life and acceptability of the diet and food supplement.

What are the possible benefits and risks of participating?
There are no anticipated risks to participants; however, changes to dietary intake will be

required for a 4-week period. Three stool samples and three urine samples will be collected and symptom, food and quality of life questionnaires will need to be completed. Routine dietary advice will be provided at the end of the study to all patients as per routine clinical care.

Where is the study run from?
King’s College London and The Royal London Hospital (UK)

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

Who is funding the study?
Study funding with research grant from Clasado (UK) ltd and departmental funding from King's College London Nutritional Sciences Division

Who is the main contact?
Bridgette Wilson
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The impact of dietary interventions for irritable bowel syndrome on luminal microbiota, symptoms, nutrient intake and quality of life: a randomised controlled trial

Study objectives
There is no difference in luminal bifidobacteria concentration between participants after four weeks of a sham diet versus four weeks of a treatment diet with added prebiotic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales Research Ethics Committee 4, 30/04/2015, ref: 15/WA/0119

Study design
4-week multicentre single-blind randomized three-armed parallel control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Irritable bowel syndrome

Interventions
1. 4 week sham diet + placebo
2. 4 week treatment diet + placebo
3. 4 week treatment diet + prebiotic

Intervention Type
Supplement

Primary outcome measure
1. Luminal bifidobacteria concentration between groups at 4 weeks
2. Adequate symptom relief between groups at 4 weeks

Secondary outcome measures
1. Difference in IBS symptoms between the three groups at 4-weeks.
2. Difference in stool consistency and stool frequency between three groups at 4-weeks
3. Difference in total and individual luminal gastrointestinal microbiota between the three groups at 4-weeks
4. Difference in faecal short chain fatty acids and pH between the three groups at 4-weeks
5. Differences in urine metabolomics between the three groups at 4-weeks
6. Difference in nutrient intake between dietary interventions at 4-weeks
7. Difference in QOL scores between the three groups at 4-weeks
8. Patient acceptability of the diet and food supplement (questionnaire)

Overall study start date
04/05/2015

Completion date
31/03/2017

Eligibility

Key inclusion criteria
1. Men and women aged 18-65 years with diarrhoea-predominant IBS (IBS-D), mixed-type IBS (IBS-M) or unsubtyped IBS (IBS-U) based on Rome III criteria who do not have a major medical condition (diabetes, psychiatric or current eating disorders), gastrointestinal disease (e.g. inflammatory bowel disease, coeliac disease) or history of previous GI surgery, except cholecystectomy and haemorrhoidectomy
2. Individuals able to give informed consent
3. Individuals naive to the dietary intervention

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
69

Total final enrolment
69

Key exclusion criteria
1. Females who report to be pregnant or lactating
2. Consumption of antibiotics, prebiotics or probiotics (in food products or as supplements) in the last 4 weeks prior to, or during the study
3. Use of unpermitted medications
4. Participants who have received bowel preparation for investigative procedures in the 4 weeks prior to the study
5. Participants who have had changes to IBS medications or dose in the 4 weeks prior to the study
6. Less than 2 days of at least moderate abdominal pain or discomfort in the screening week
7. Individuals with additional specific dietary needs
8. Individuals with excess alcohol or caffeine intake as assessed by diet questionnaires as these substances may confound symptom results

Date of first enrolment
04/05/2015

Date of final enrolment
09/09/2016

Locations

Countries of recruitment
England

United Kingdom

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

Study participating centre
Barts and the London NHS Trust
London
United Kingdom
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Sponsor information

Organisation
King's College London

Sponsor details
1.8 Hodgkin Building
Guy’s Campus
London
England
United Kingdom
SE1 1UL

Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

Organisation
Guy's and St Thomas' NHS Foundation Trust

Sponsor details
R&D Department
16th Floor
Tower Wing
Great Maze Pond
London
England
United Kingdom
SE19RT

Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/Home.aspx

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Industry

Funder Name
Clasado (UK) Ltd

Funder Name
King's College London, Nutritional Sciences Division (UK)

Results and Publications

Publication and dissemination plan

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	01/06/2020	07/08/2020	Yes	No
HRA research summary			28/06/2023	No	No
Results article		14/06/2023	07/04/2025	Yes	No