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The effect of a low FODMAP diet on luminal microbiota, fermentation and symptoms

Submission date	Recruitment status	[_] Prospectively registered
22/01/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/03/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/11/2013	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
The effect of a low FODMAP diet on luminal microbiota, fermentation and symptoms: A randomised controlled trial

Study objectives
H0: there will be no significant difference in the concentration of faecal bifidobacteria in patients with Irritable Bowel Syndrome (IBS) following a low FODMAP diet (intervention) compared with those following a normal diet (control) for four weeks.

H1: there will be a significant difference in the concentration of faecal bifidobacteria in patients with IBS following a low Fermentable Oligo-, Di-, and Monosaccharides and Polyol (FODMAP) diet (intervention) compared with those following a normal diet (control) for four weeks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Guy's Research Ethics Committee, 11/11/2009, ref: 09/H0804/89

Study design
Randomised controlled parallel group trial

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 contact details below to request a patient information sheet.

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

Interventions
4-week low FODMAP diet compared to usual diet.
Patients in the intervention group will receive individualised dietary advice. A low FODMAP diet is a diet low in poorly absorbed fermentable carbohydrates. Patients will follow the diet for 4 weeks. The total duration of the study will be 5 weeks.

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
To assess the effect of a low FODMAP diet on faecal microbiota in patients with IBS.
Faecal samples will be collected at baseline and at 4 weeks.

Secondary outcome measures
1. To assess the effect of a low FODMAP diet on faecal Short Chain Fatty Acid (SCFA), pH and faecal water in patients with IBS.
2. To assess the effect of a low FODMAP diet on symptoms in patients with IBS.
3. To assess the effect of a low FODMAP diet on stool consistency and frequency in patients with IBS.
4. To assess the nutritional adequacy of a low FODMAP diet in patients with IBS.
5. To assess the acceptability of a low FODMAP diet in IBS patients.
6. Weight and height.
Outcomes will be assessed at baseline and at 4 weeks. Patients will keep a symptom diary and diet diary, and 2 questionnaires will be used to assess nutritional adequacy, FODMAP intake and diet acceptability.

Overall study start date
01/02/2010

Completion date
31/12/2010

Eligibility

Key inclusion criteria
Patients will be recruited from Gastrointestinal and Dietetic Outpatient clinics at Guys and St Thomas NHS Foundation Trust, London, UK.
1. Adult patients aged 18-65 years
2. Identified as having IBS based on Rome III criteria
3. Symptoms including bloating and/or diarrhoea

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants

40

Key exclusion criteria
1. Patients with any other gastrointestinal disease or gastrointestinal surgery
2. Patients whose major IBS symptom is constipation
3. Patients receiving lactulose or any other probiotic or prebiotic substances in the four weeks prior to the study
4. Patients who have taken antibiotics in the 4 weeks prior to the study
5. Patients who have received bowel preparation for investigative procedures in the 4 weeks prior to the study
6. Patients with any other significant major organ disorders, including diabetes, psychiatric and current eating disorders
7. Patients who report to be pregnant or lactating
8. Patients who have had changes to IBS medications or dose in the 4 weeks prior to the study

Date of first enrolment
01/02/2010

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
4.06 Franklin Wilkins Building
London
United Kingdom
SE1 9NH

Sponsor information

Organisation
King's College London (UK)

Sponsor details
Hodgkin Building
Guy's Campus Kings College London
LondonSE1 1UL
UNITED KINGDOM
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Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
University/education

Funder Name
King's College London (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2012		Yes	No