

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

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| Submission date 22/01/2010 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 08/03/2010 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 14/11/2013 | Condition category Digestive System | <input type="checkbox"/> Individual participant data |

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

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

London SE1 1UL

UNITED KINGDOM

London

England

United Kingdom
SE1 1UL

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 |