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Dietary interventions for irritable bowel syndrome

Submission date
27/06/2012

Recruitment status
No longer recruiting

Registration date
28/08/2012

Overall study status
Completed

Last Edited
16/11/2020

Condition category
Digestive System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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 quality of life. A diet with an altered amount of carbohydrates (e.g. the types of fruits and vegetables) might be effective for 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 in the bowel. Probiotics are friendly bacteria added to foods that can increase the amount of bifidobacteria in the bowel. This study will investigate the effect of this diet with a probiotic 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. Dietary intake
5. Quality of life
The effect of dietary change on symptoms and the bacteria in the bowel in the longer term will also be studied.

Who can participate?
Patients of Guy's and St Thomas' NHS Foundation Trust or St George's Healthcare Trust aged 18-65 with IBS

What does the study involve?
The study incorporates three study centre visits, one before the 4-week study period, one after the 4-week study period and one visit at 12 months. There may also need to be one initial visit prior to the baseline visit in order to obtain consent if the patient is not identified in clinic, but screened from the referral letter.

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. Two stool 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?
The study will be run from King's College London and St George's Healthcare Trust

When is the study starting and how long is it expected to run for?
Recruitment will continue until September 2014

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Heidi Staudacher, Research Dietitian
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

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
Current study hypothesis as of 24/01/2013:
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 probiotic.

Previous study hypothesis until 24/01/2013:
There is no difference in luminal bifidobacteria concentration between participants after four weeks of a sham diet versus four weeks of a fermentable carbohydrate restriction with added probiotic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London-Fulham, 08/10/2012, ethics no. 12/LO/1402

Primary study design
Interventional

Study design
2 x 2 factorial design randomised controlled trial

Study type(s)
Treatment

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

Interventions
Current interventions as of 24/01/2013:
4-week treatment diet + placebo
4-week treatment diet + added probiotic
4-week week sham diet + placebo
4-week sham diet + added probiotic

Previous interventions until 24/01/2013:
4-week fermentable carbohydrate restriction + placebo
4-week fermentable carbohydrate restriction + added probiotic
4-week week sham diet + placebo
4-week sham diet + added probiotic

Intervention Type
Mixed

Primary outcome(s)
1. Luminal bifidobacteria concentration between groups at 4 weeks

Added 05/08/2014:
2. Proportion of participants with adequate relief of IBS symptoms at 4 weeks

Key secondary outcome(s)
1. Difference in total and individual luminal gastrointestinal microbiota at 4 weeks
2. Difference in faecal short chain fatty acids and pH between groups at 4 weeks
3. Difference in IBS symptoms between groups at 4 weeks
4. Difference in stool consistency between groups at 4 weeks
5. Difference in nutrient intake between groups at 4 weeks
6. Difference in quality of life (QOL) scores between groups at 4 weeks

Completion date
30/09/2014

Eligibility

Key inclusion criteria
1. Men and women aged 18-65 years with IBS-D, IBS-M or unsubtyped IBS based on Rome III criteria who do not have a major medical condition (diabetes, psychiatric or current eating disorders)
2. Gastrointestinal disease (e.g. inflammatory bowel disease, coeliac disease)
3. History of previous GI surgery, except cholecystectomy and haemorrhoidectomy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
95

Key exclusion criteria
1. Females who report to be pregnant or lactating
2. Consumption of antibiotics, pre or probiotics (in food products or as supplements) in the last 4 weeks prior to, or during the study
3. Use of unpermitted medications (e.g. biological therapies)
4. Patients who have received bowel preparation for investigative procedures in the 4 weeks prior to the study
5. Patients who have had changes to IBS medications or dose in the 4 weeks prior to the study
6. Abdominal pain or discomfort for less than 2 days in the screening week, the frequency threshold recommended for clinical trials. Exclusion of those with minimal symptoms is recommended, and only those that experience pain on at least two days will be included.
7. Individuals with additional specific dietary needs

Date of first enrolment
01/09/2012

Date of final enrolment
30/09/2014

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
King's College London
London
United Kingdom
SE1 9NH

Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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	01/10/2017		Yes	No
Results article	results	01/03/2018		Yes	No
Results article	results	23/10/2020	16/11/2020	Yes	No