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Bacterial supplementation as treatment for the irritable bowel syndrome: a randomised double-blind placebo-controlled study

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 16/02/2015	**Condition category** 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
N0265122367

Study information

Scientific Title
Bacterial supplementation as treatment for the irritable bowel syndrome: a randomised double-blind placebo-controlled study

Study objectives
To assess the tolerance and efficacy of Synbiotic Cocktail 2000 in symptom reduction in the irritable bowel syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Double-blind randomised placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Digestive System: Irritable bowel syndrome (IBS)

Interventions
ASSESSMENT ON ADMISSION INTO TRIAL: History and examination, normal blood tests and a previously normal flexible sigmoidoscopy.

ASSESSMENT DURING STUDY PERIOD: All patients will be randomised to receive either the placebo or Synbiotic cocktail 2000 daily for 8 weeks. Prior to this period, there will be a run in period of 2 weeks where patients will record baseline gastrointestinal symptoms on a weekly basis as well as bowel frequency and consistency on a daily basis. A previously validated patient diary will be used scoring abdominal pain, bloating, number and consistency of stool and level of flatulence completed on a weekly basis. After the 2 week run in period, a study period involving Synbiotic or placebo intake will last for 8 weeks. A final questionnaire would be sent out to all patients 6 months post study period, using the same format. Prior to commencement and

directly after treatment or placebo period, patients will undergo a hydrogen breath test to ensure bacterial supplementation has not resulted in bacterial overgrowth.

REMOVAL FROM STUDY: Patients may be removed from the study if one or more of the following occurs: Protocol violation or non-compliance on part of the patient, refusal of the patient to continue treatment and a decision by the investigator that termination is in the patient's best medical interest (or a significant unrelated medical illness or complication).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Synbiotic Cocktail 2000

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
13/04/2003

Completion date
13/04/2008

Eligibility

Key inclusion criteria
1. Any patient seen in gastroenterology outpatient clinics at University Hospital Birmingham who fulfils the Rome criteria II for IBS would be offered entry into the trial
2. Patients without a history of malabsorption, previous abdominal surgery, diverticulitis or other organic intestinal disease

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
100 patients (50 in each arm).

Key exclusion criteria

1. Pregnancy
2. Any form of mental disorder
3. Severe systemic illness

Date of first enrolment
13/04/2003

Date of final enrolment
13/04/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
GI Medicine
Birmingham
United Kingdom
B29 6JD

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (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