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Investigation of the efficacy of a novel galacto-oligosaccharide prebiotic (B12GOS) in the treatment of irritable bowel syndrome

Submission date 28/10/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/11/2005	**Overall study status** Completed	
Last Edited 17/05/2011	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Study information

Scientific Title

Study objectives
Irritable bowel syndrome (IBS) is the commonest functional gastrointestinal disorder. Symptoms occur in the absence of any demonstrable organic disease. Symptoms arise as a consequence of

either abnormality of the intestinal motility or sensation or as a combination of the two. Abnormal small intestinal and colonic motility has been demonstrated in IBS patients. These may lead to the onset of pain as well as bloating and if the abnormal motility results in changes in intestinal transit, constipation and diarrhoea.

Hypothesis:
1. The principal research objective is to assess the tolerability of the new synthesised galacto-oligosaccharide prebiotic (B12GOS) in patients with irritable bowel syndrome (IBS), to evaluate the effect of B12GOS on the faecal microflora of patients with IBS, and to assess the effect of B12GOS on the concentration of colonic fermentation end products (short chain fatty acids) in the faecal samples of patients with IBS
2. To examine B12GOS efficacy verses placebo in IBS patients on the subjects global assessment of relief (SGA), severity of patient symptoms, stool frequency and consistency and quality of life

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yes. Approved October 2005.

Study design
Interventional, single blind, randomised, stratified, parallel design

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Single blind, randomised, stratified, parallel design in patients with diarrhoea predominant IBS (D-IBS), constipation predominant IBS (C-IBS) and alternating IBS (A-IBS). The single blind nature of the trial is in order that the placebo can be administered in each case prior to the prebiotic.

Patients randomised to 1 of 3 groups. Design will then consist of an initial 2 week baseline period followed by 2 treatment periods of 4 weeks each, separated by a 2 week 'wash out' phase. During the 1st treatment period patients will be asked to drink once daily before breakfast either 7.0 g (2 groups) or 3.5 g (one group) chocolate or banana flavoured placebo. After the 2 week 'wash out' period patients will be asked to drink once daily, before breakfast, either 7.0 g or 3.5 g of chocolate or banana flavoured B12GOS, or 7.0 g chocolate or banana flavoured placebo. On day 1 patient numbers will be assigned and stratified according to D-IBS, C-IBS, A-IBS. Randomisation table to be obtained from the internet.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Galacto-oligosaccharide prebiotic (B12GOS)

Primary outcome(s)
To assess the tolerability of B12GOS in IBS patients and to assess the B12GOS-induced changes in:
1. The faecal microbiota of patients with IBS using culture independent methodology
2. The concentration of colonic fermentation end-products (short fatty acids) in the faecal samples

Key secondary outcome(s))
To examine the efficacy of B12GOS versus placebo on Subjects Global Assessment of relief (SGA), severity of patient symptoms, stool frequency and consistency and quality of life.

Completion date
01/12/2006

Eligibility

Key inclusion criteria
Only patients fulfilling the Rome II criteria for diagnosis of IBS will be included in the study. All will have normal haematological and biochemical indices and no abnormal findings on barium enema or colonoscopy undertaken within the previous five years. Patients will be categorised into diarrhoea predominant (D-IBS), constipation predominant (C-IBS) or altering sub groups of IBS (A-IBS) according to published criteria.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients with evidence of organic disease of the gastrointestinal tract such as tumour, inflammatory bowel disease etc. as shown by endoscopic or radiological evaluation of the bowel within the previous 5 years
2. Patients with abnormal laboratory tests, positive stool cultures in patients with diarrhoea predominant IBS or abnormal proctoscopy or abdominal ultrasound which requires further investigation
3. Functional disorder of upper gastrointestinal tract for which treatment has not been stable for past three months
4. Use of other investigational drugs within prior month or intention to use such drugs during the course of the study
5. Intention to use regularly other medication or investigational agents that affect

gastrointestinal motility
6. Ingestion of products containing pre- and or pro-biotics in the last two weeks before the trial commences
7. Received antibiotics in the previous three months

Date of first enrolment
01/02/2006

Date of final enrolment
01/12/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Gastroenterology & Nutrition
London
United Kingdom
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Sponsor information

Organisation
Clasado Ltd (UK)

ROR
https://ror.org/04e5xac72

Funder(s)

Funder type
Industry

Funder Name
Clasado Ltd (UK)

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	01/03/2009		Yes	No