

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/11/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/05/2011	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

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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.

Overall study start date

01/02/2006

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

Age group

Adult

Sex

Both

Target number of participants

A total of 66 patients.

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**

England

United Kingdom

Study participating centre

Department of Gastroenterology & Nutrition

London

United Kingdom

NW10 7NS

Sponsor information

Organisation

Clasado Ltd (UK)

Sponsor details

11 Warren Yard
Wolverton Mill
Milton Keynes
United Kingdom
MK12 5NW

Sponsor type

Industry

Website

<http://www.clasado.com>

ROR

<https://ror.org/04e5xac72>

Funder(s)**Funder type**

Industry

Funder Name

Clasado Ltd (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	01/03/2009		Yes	No