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Assessment of the probiotic symprove as a dietary supplement in patients with irritable bowel syndrome

Submission date	Recruitment status	[_] Prospectively registered
27/10/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/12/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/05/2014	Digestive System	

Plain English summary of protocol

Background aims and objectives
Irritable bowel syndrome (IBS) can be a painful and debilitating condition; it is associated with many different symptoms, the most common of which is abdominal (stomach) pain. It is one of the most frequent disorders seen by doctors at general gastroenterology clinics. Conventional treatment of IBS involves a combination of drugs, supportive psychotherapy and dietary manipulation; however, current drugs dont work very well in many sufferers and often have unpleasant and severe side effects. The main aim of this study is to investigate the potential benefits of using a particular multi-strain (more than one bacteria) liquid probiotic (Symprove) in IBS. Benefits will be measured by asking patients to answer a special questionnaire that has been designed as a means for clinicians to monitor and assess IBS symptoms in patients under their care.

Who can participate?
The study aims to recruit adults, aged 18-65 years, who have had moderate to severe IBS for at least 6 months.

What does the study involve?
All patients would undergo an interview, physical examination and routine studies before the start of the trial. These studies would include many tests that are used routinely for IBS workup including blood tests and stool sampling. Patients will be randomly allocated into two groups; one group will receive the probiotic Symprove taken as a drink once a day, while the other will receive a similar placebo (dummy) drink once a day. Each participant will take probiotic or placebo for a period of three months followed by a two-month follow-up period, so the total length of the study for each participant will be about five months. Participants will visit the clinic every four weeks for monitoring and some of the studies undertaken at the start of the study may be repeated after one and three months treatment as part of routine care and at the end of the follow-up period of the study.

What are the possible benefits and risks of participating?
Many members of the public with IBS have taken this probiotic for their IBS symptoms.

Anecdotally they have spoken of feeling better with a lessening of symptoms when taking the probiotic but this was not done in the context of a clinical trial. It is expected that participants in this study will have similar benefits. Some participants may experience some loosening of bowel motions in the first few days as the bacteria colonise the large bowel. No other adverse effects are anticipated.

Where is the study run from?
The study will be undertaken at Kings College Hospital, London (UK).

When is the study starting and how long is it expected to run for?
The study started in September 2008 and will run for about 2 years.

Who is funding the study?
The trial is funded by Kings College Hospital NHS Foundation Trust (UK).

Who is the main contact?
Prof. Ingvar Bjarnason (Chief investigator), Ingvar.bjarnason@kcl.ac.uk
Dr Guy Sisson (Lead Investigator) , Guy.sisson@dvh.nhs.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
05LG04

Study information

Scientific Title

Assessment of the probiotic symprove as a dietary supplement in patients with irritable bowel syndrome: a double-blind randomised placebo-controlled trial

Study objectives
Current hypothesis as of 22/10/2013:
The probiotic Symprove when taken as a dietary supplement can significantly improve symptoms in patients with irritable bowel syndrome (IBS).
The above protocol change was made prior to the trial opening.

Previous hypothesis:
The probiotic symprove when taken as a dietary supplement can significantly improve the quality of life (QOL) of patients with irritable bowel syndrome (IBS).

As of 10/05/2011 the anticipated end date for this trial has been extended from 01/04/2010 to 31/07/2011 as there has been a delay in recruiting patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bromley NRES Committee gave approval in July 2008 (ref: 08/H0809/31). Subsequent SSI (site specific inquiry) was confirmed by a chairman's action by the local NRES committee in August 2008.

Study design
Double-blind randomised placebo-controlled 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 the contact details below to request a patient information sheet

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

Interventions
Symprove probiotic dietary supplement (1 ml/kg) or placebo. Following a 1-week run-in period, all patients will receive 12 weeks of treatment (either placebo or active treatment) followed by a further 4-week follow-up. Patient randomisation in a 2:1 ratio active:placebo.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Symprove

Primary outcome measure
Current primary outcome measures as of 22/10/2013:
1. Efficacy change in IBS Symptom Severity Score (IBS-SSS) from baseline to week 12
2. Safety tolerability of the multistrain probiotic
The above change in protocol was made prior to the trial opening

Previous primary outcome measures:
Improvement in quality of life (QOL) as measured by a validated QOL questionnaire on week 12 of the study

Secondary outcome measures
Current secondary outcome measures as of 22/10/2013:
Improvements in symptoms and QoL as described by:
1. Change in IBS-QoL score from baseline to week 12
2. Change in IBS-SSS component scores at week 12
3. Changes in IBS-SSS and QoL between week 12 and 16
The above change in protocol was made prior to the trial opening

Previous secondary outcome measures:
1. Improvement in Sleep Quality Assessment
2. Improvement in Global Symptom Severity Score and specific symptom sub-scores (abdominal pain, bloating, stool frequency and stool consistency)
These will all be assessed at 4 weekly intervals (4, 8 and 12 weeks of treatment and week 16 - 4 weeks after treatment)

Overall study start date
01/10/2008

Completion date
31/07/2011

Eligibility

Key inclusion criteria
1. Aged between 18 - 65 years, either sex
2. A firm diagnosis of IBS (ROME III criteria)
3. Moderate to severe symptoms

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
186 patients

Key exclusion criteria
1. Diagnosis of inflammatory bowel disease or other organic bowel disease
2. Significant co-morbidity
3. Major psychological disorders
4. Previous/current history of alcohol or drug dependence
5. Pregnancy

Date of first enrolment
01/10/2008

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Gastroenterology
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
Kings College Hospital (UK)

Sponsor details

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United Kingdom
SE5 9RS
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Sponsor type
Hospital/treatment centre

Website
http://www.kch.nhs.uk

ROR
https://ror.org/044nptt90

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (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	01/07/2014		Yes	No