

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

<b>Submission date</b> 27/10/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/12/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/05/2014	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## 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 don't 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

### Contact name

Dr Guy Sisson

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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

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**Sponsor information****Organisation**

Kings College Hospital (UK)

**Sponsor details**

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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?
<a href="#">Results article</a>	results	01/07/2014		Yes	No