

# Assessment of the probiotic Symprove as a dietary supplement in patients with symptomatic diverticular disease

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<b>Registration date</b> 08/02/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/12/2017	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

In diverticulosis, small bulges develop in the lining of the large intestine (colon). Diverticulitis is when these bulges become inflamed or infected. Diverticulitis is an extremely common disease particularly found in elderly patients. Many patients with diverticulitis have symptoms such as diarrhoea, constipation and abdominal pain, similar to Irritable Bowel Syndrome (IBS). Different treatments have been proposed but they are unproven or controversial. It is thought that intestinal bacteria may be involved in the symptoms. As the probiotic dietary supplement Symprove has been found to reduce the symptoms of IBS, this study aims to test Symprove in patients with diverticulitis.

### Who can participate?

Patients aged between 18 and 80 with diverticulitis.

### What does the study involve?

Participants are randomly allocated to be treated with either Symprove or placebo (dummy treatment) for 12 weeks followed by a further 4-week follow-up.

### What are the possible benefits and risks of participating?

Symprove may be able to help reduce the severity of diverticular disease symptoms such as pain, diarrhoea, constipation and bloating. There are no known risks of drinking Symprove.

### Where is the study run from?

King's College Hospital Gastroenterology Department (UK).

### When is the study starting and how long is it expected to run for?

January 2013 to December 2014.

### Who is funding the study?

King's College Hospital NHS Foundation Trust (UK).

Who is the main contact?  
Prof. Ingvar Bjarnason

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Ingvar Bjarnason

**Contact details**  
Department of Gastroenterology  
King's College Hospital  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**  
Assessment of the probiotic Symprove as a dietary supplement in patients with symptomatic diverticular disease: a double blind randomised placebo controlled trial

**Study objectives**  
The probiotic Symprove when taken as a dietary supplement can reduce symptom severity and significantly improve the quality of life (QOL) of patients with symptomatic diverticular disease.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Health Research Authority, NRES Committee London - Riverside, Bristol Research Ethics Committee Centre, 10/12/2012, REC ref: 12/LO/1695, IRAS project ID: 115448

**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**

Diverticular disease

**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**

Supplement

**Primary outcome measure**

Improvement in Global Symptom Severity Score and specific symptom sub-scores (abdominal pain, bloating, stool frequency and stool consistency)

**Secondary outcome measures**

1. Improvement in quality of life (QOL) as measured by a validated QOL questionnaire on week 12 of the study
2. Improvement in Sleep Quality Assessment

**Overall study start date**

01/01/2013

**Completion date**

31/12/2014

**Eligibility****Key inclusion criteria**

1. Have a documented episode of diverticulitis as assessed clinically, on CT scans and a raised serological markers of inflammation
2. Have problematic symptoms associated with established diverticular disease
3. Aged between 18 and 80 years
4. Are on no treatment or have been on stable medication for at least 6 weeks for diverticular

disease

5. Willing and able to provide a written informed consent

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

200

**Key exclusion criteria**

1. Aged less than 18 years and greater than 80 years
2. Severe disease (ongoing severe active diverticulitis) as defined by hemoglobin < 8.0 g/dl, white blood cell count >20,000 cells/mm<sup>3</sup>, temperature >38.5°C, albumin < 25 g/dl
3. Diverticular complications such as recto-vaginal or bladder fistula, abscess, etc.
4. Severe respiratory, cardiovascular, neurological, psychiatric, rheumatological diseases
5. Undergone major intestinal resections
6. Patients with malignancy
7. On NSAIDs
8. Pregnancy or actively seeking pregnancy
9. History of intolerance or allergy to probiotics
10. Current drug or alcohol dependence syndrome
11. Pregnancy
12. Patients with severe learning difficulties

**Date of first enrolment**

01/01/2013

**Date of final enrolment**

31/12/2014

**Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

King's College Hospital

London

United Kingdom  
SE5 9RS

## Sponsor information

### Organisation

King's College Hospital (UK)

### Sponsor details

c/o Prof. Ingvar Bjarnason  
Department of Gastroenterology  
King's College Hospital  
Denmark Hill  
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England  
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SE5 9RS

### Sponsor type

Hospital/treatment centre

### Website

<http://www.kch.nhs.uk>

### ROR

<https://ror.org/01qz4yx77>

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

King's College Hospital NHS Foundation 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/05/2017		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No