

# Assessment of a multistrain probiotic in inflammatory bowel disease (IBD)

<b>Submission date</b> 28/06/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/08/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/04/2017	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**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**  
080609/02; KCH1636

# Study information

## Scientific Title

Assessment of a multistrain probiotic (symprove) as a dietary supplement in patients with inflammatory bowel disease who are in 'clinical' remission

## Study objectives

Regular use of this multistrain probiotic may have anti-inflammatory properties and help improve the residual symptoms of inflammatory bowel disease (IBD) experienced by patients in 'clinical remission'.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Outer South East London Research Ethics Committee, 01/10/2009, ref: 09/H0805/37

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Other

## Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

## Health condition(s) or problem(s) studied

Inflammatory bowel disease (ulcerative colitis and Crohn's disease)

## Interventions

160 patients with mild/moderate IBD will be randomly assigned (1:1 UC and 1:1 Crohn's disease) to receive 1 ml/kg/day (max 100 ml) of probiotic or placebo for 4 weeks.

## Intervention Type

Drug

## Phase

Phase II

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

Symprove

**Primary outcome measure**

Improvement in Inflammatory Bowel Disease Questionnaire (IBDQ) score at week 4

**Secondary outcome measures**

Reduction in faecal calprotectin at week 4

**Overall study start date**

01/07/2010

**Completion date**

01/07/2011

## **Eligibility**

**Key inclusion criteria**

1. Patients aged 18 - 65 years, either sex
2. Minimum 6 months history of inflammatory bowel disease
3. Confirmed both endoscopically and histologically
4. Three months of 'stable clinical remission' - including no change in treatment during the preceding 3 months

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Both

**Target number of participants**

160 (80 each with ulcerative colitis and Crohn's disease)

**Key exclusion criteria**

1. Aged less than 16 years and greater than 65 years
2. Severe disease or current disease flare
3. Current use of biological or immunosuppressive treatments (including infliximab, adalimumab, methotrexate, azathioprine, 6-mercaptopurine, cyclosporin). Patients who are taking azathioprine or 6-mercaptopurine who have been stable on treatment for a minimum of 12 weeks without major side effects or adverse events will not be excluded.
4. Previous complicated bowel resections or multiple bowel resections
5. Pregnancy or actively seeking pregnancy

6. History of intolerance or allergy to probiotics
7. Significant comorbid conditions (to be judged by the research doctor at assessment)
8. Significant psychiatric comorbidity (to be judged by the research doctor at assessment)
9. Current drug or alcohol dependence syndrome

**Date of first enrolment**

01/07/2010

**Date of final enrolment**

01/07/2011

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

King's College Hospital

London

United Kingdom

SE5 9RS

## Sponsor information

**Organisation**

Kings College Hospital NHS Foundation Trust (UK)

**Sponsor details**

Kings College Hospital

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**Sponsor type**

Hospital/treatment centre

**Website**

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

**ROR**

<https://ror.org/01n0k5m85>

## **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