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

Submission date	Recruitment status	[ ] Prospectively registered
28/06/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/08/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/04/2017	Digestive System	[ ] 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 immunosupressive 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
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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