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

Submission date
05/02/2013

Recruitment status
No longer recruiting

Registration date
08/02/2013

Overall study status
Completed

Last Edited
19/12/2017

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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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 assesses 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 stabile 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/mm3, 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
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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?
Results article	results	01/05/2017		Yes	No
HRA research summary			28/06/2023	No	No