

Measuring the impact of dietary supplementation with prebiotics on markers of inflammation in ulcerative colitis

Submission date 08/11/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/11/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/08/2022	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Ulcerative colitis (UC) is a condition which cause long-term inflammation (swelling) in the colon and rectum (the last part of the large intestine). The exact cause is unknown, but some think that it may be because the immune system attacks the healthy tissue of the gut (autoimmune disease). There is currently no cure, and so the main aim of treatment is to reduce the symptoms (remission) and prevent the disease from “flaring up” and becoming active again. Even when the disease is in remission, many patients still experience symptoms such as bloating, diarrhoea and abdominal (tummy) pain. Studies looking at UC in people and in the lab have found that some types prebiotics (an ingredient in some foods which helps increase the amount of 'good' bacteria in the gut) may help reduce inflammation by signalling to the immune system through specific pathways. The way this works is unclear however and requires further research. The aim of this study is to find out whether consuming prebiotics daily has an effect on gut inflammation in people with UC.

Who can participate?

Men and women aged 16-65 who have ulcerative colitis.

What does the study involve?

All participants are provided with a six week supply of Bimuno prebiotic dietary supplement and are asked to take this daily for six weeks. Before starting and at the end of the trial participants are asked to fill in a food and bowel diary to tell the researchers about what their normal diet, gut symptoms and bowel habits are like in to have information to compare the results to. Participants provide blood, stool and urine samples at the start of the trial and after six weeks of taking the supplements to measure markers of immunity and inflammation.

What are the possible benefits and risks of participating?

Bimuno is a prebiotic widely available in the UK, participants will be provided with this for free for six weeks to supplement their normal diet. The main researcher is a qualified Dietitian and

will be able to answer questions about diet and at the end of the study provide any dietary advice that may be relevant to the participant (not during the trial though as diet should stay the same). There are no anticipated risks to taking part.

Where is the study run from?

1. Guy's Hospital, London (UK)
2. Royal London Hospital, London (UK)

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

May 2016 to March 2018

Who is funding the study?

1. Clasado Ltd (UK)
2. King's College London, Diabetes and Nutritional Sciences Division (UK)

Who is the main contact?

Miss Bridgette Wilson
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Contact information

Type(s)

Public

Contact name

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Contact details

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Additional identifiers

Integrated Research Application System (IRAS)

208755

Protocol serial number

IRAS ID: 208755

Study information

Scientific Title

The effect of six-weeks dietary supplementation with prebiotics (Trans-galactooligosaccharide (B-GOS) on the expression of genes involved in immunity and inflammation in peripheral blood of adult participants with mildly active ulcerative colitis in an open label pilot study

Acronym

Prebiotics in immunity and inflammation

Study objectives

This is an exploratory study to investigate the impact on markers of inflammation and immunity of dietary prebiotic supplementation in gastrointestinal inflammation. This study is intended to generate hypotheses for future research into dietary interventions for gut inflammation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Yorkshire and the Humber - Bradford Leeds Research Ethics Committee, 04/10/2016, ref: 16/YH/0438

Primary study design

Interventional

Study design

Open label multi-centre non randomised study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Ulcerative Colitis

Interventions

All participants will be required to take one 5.5g sachet which contains 2.7g prebiotic food supplement (Bimuno, Clasado) daily for six weeks. This will be reconstituted with water and participants will be encouraged to take the sachet at the same time each day.

Participants provide blood, urine and stool samples for analysis at baseline and six weeks.

Intervention Type

Supplement

Primary outcome(s)

Expression of genes involved in immunity and inflammation in peripheral blood is measured using mRNA microarray to identify target genes and qPCR to quantify changes in gene expression, at baseline and 6 weeks.

Key secondary outcome(s)

All secondary outcome measures will be assessed at baseline before the intervention begins and at the end of six weeks, blood, stool and urine samples will be collected at these two timepoints in order to assess the following:

1. Serum or plasma protein expression will be assessed using enzyme linked immunosorbent assays (ELISA) and standard blood laboratory techniques
2. Faecal markers of inflammation such as faecal calprotectin and human beta-defensin 2 will be measured using ELISA
3. Metabolomic profiles in urine are measured using mass spectrometric based approaches in urine metabolomics
4. Gut microbiota metabolites indicators including proteases, SCFAs, and VOC will be measured using standard laboratory techniques including gas liquid chromatography
5. pH will be measured on fresh stool using a solid probe pH meter
6. Bacterial communities and function will be measured via sequencing techniques

Completion date

30/03/2018

Eligibility

Key inclusion criteria

1. Men and women aged 16-65 years
2. Women who are not currently pregnant or lactating
3. Mildly active UC defined by Gastroenterologist's opinion and supported one or more of
 - 3.1. CRP above normal for referring centre
 - 3.2. Faecal calprotectin greater than 150 ug/g
 - 3.3. Recent endoscopic evidence of active disease
4. No anticipated changes to dose or type of UC medication for the seven week trial period
5. Patients without another major medical condition (e.g. diabetes, psychiatric or current eating disorders), other gastrointestinal disease or condition (e.g. Crohn's disease, coeliac disease, lactose or dairy allergy), known enteropathogen or history of previous major GI surgery, except cholecystectomy, appendectomy and haemorrhoidectomy
6. Participants who have not received bowel preparation for investigative procedures in the four weeks prior to the study
7. Participants who have not taken antibiotics, prebiotics or probiotics (in other food products or as supplements) in the four weeks prior to, or during the study
8. Individuals able to give informed consent
9. Individuals willing to participate

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

18

Key exclusion criteria

1. Factors affecting immunity and inflammation
 - 1.1. Started azathioprine, mercaptopurine or thioguanine therapy less than 12 weeks previously or who have changed dose in the previous 6 weeks
 - 1.2. Started 5-asa (mesalazine) therapy less than 8 weeks previously or who have changed dose in the previous 2 weeks
 - 1.3. Prescribed use of steroids
 - 1.4. Prescribed use of methotrexate
 - 1.5. Prescribed use of the immunosuppressant drugs ciclosporin and tacrolimus
 - 1.6. Prescribed use of anti-inflammatory drugs e.g. infliximab, vedoluzimab, golimumab, adolimubab
 - 1.7. Regular use of non-steroidal anti-inflammatory drugs (NSAIDs)
2. Factors which may confound impact of prebiotic supplementation
 - 2.1. Use of antibiotics four weeks prior to starting intervention
 - 2.2. Use of prebiotics or probiotics (in other food products or as supplements) four weeks prior to starting intervention
 - 2.3. Bowel preparation for a diagnostic procedure e.g. colonoscopy four weeks prior to starting intervention
 - 2.4. Regular use of other supplements/medications that may affect the luminal microenvironment of the intestine (e.g. Orlistat, Lactulose)

Date of first enrolment

29/11/2016

Date of final enrolment

30/08/2017

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Guy's Hospital

Guy's and St Thomas' NHS Foundation Trust
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre

The Royal London Hospital

Whitechapel Road
London
United Kingdom
E1 1BB

Sponsor information

Organisation

King's College London

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

Industry

Funder Name

Clasado Ltd

Funder Name

King's College London, Diabetes and Nutritional Sciences Division

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/10/2021	10/08/2022	Yes	No
HRA research summary			28/06/2023	No	No