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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/11/2016	**Overall study status** Completed	
Last Edited 10/08/2022	**Condition category** Digestive System	

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). Their 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
bridgette.wilson@kcl.ac.uk

Contact information

Type(s)
Public

Contact name
Miss Bridgette Wilson

Contact details
King's College London
Office 4.103
150 Stamford Street
London
United Kingdom
SE1 9NH
+44 20 7848 4552
bridgette.wilson@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number
208755

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Open label multi-centre non randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/05/2016

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

Age group
Adult

Sex
Both

Target number of participants
18

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
England

United Kingdom

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

Sponsor details
1.8 Hodgkin Building
Guy's Campus
London
England
United Kingdom
SE1 1UL

Sponsor type
University/education

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/10/2018

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