ISRCTN68739743 https://doi.org/10.1186/ISRCTN68739743

Preventing postoperative relapse of Crohn's disease by using IgG4 guided exclusion diets

Submission date
06/02/2013

Recruitment status
No longer recruiting

Registration date
15/02/2013

Overall study status
Completed

Last Edited
25/06/2020

Condition category
Digestive System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Crohns disease is chronic inflammatory condition of gastro-intestinal tract that affects 60,000 people in the UK. The etiology is unclear and there is no definite cure. 80% of patients with Crohns disease will undergo surgery in their lifetime. About 70-80% of them will have endoscopic recurrence within 1 year. Endoscopic recurrence correlates well with subsequent clinical recurrence. Effective post surgical therapy with drugs, diet or a combination of both may decrease recurrences and associated morbidity and re-operation rates. Inspite of medical therapy, clinical recurrence rates are as high as 45% within the first year and increases progressively with time. In this study, we investigate the possibility of reducing recurrence rates in such patients using IgG4 based exclusion diets. Hypersensitivity to certain food types has been studied as one of the contributing factors in Crohns disease. In this study, individual patients immune response to different food types (antigens) is measured using IgG4 antibody titers against 14 common foods types (cheddar cheese, egg white, egg yolk, rice, wheat, peanuts, soya, tomato, potato, milk, cheese, chicken, lamb, pork). Four food types with highest antibody titres (and hence most severe immune response) will then be excluded from the patient s diet. Our study aims to further the knowledge in potential role of IgG4 in Crohns disease by defining the source of IgG4 anti-food antibodies in patients with Crohns disease.

Who can participate?
Patients who undergo surgery for Crohns disease at St Georges hospital will be invited to participate in the study. They should be 16 years or over and should be able to provide informed consent. Those who agree to dietary restriction will be included in the study. Patients who are diagnosed with other autoimmune disorders and those who undergo surgery for isolated perianal Crohns disease will be excluded from the study.

What does the study involve?
Patients who consent to participate in the study will be randomly assigned to control group or intervention group. At recruitment, patients in the intervention group will be advised to exclude 4 types of food from their diet based on blood tests. The diet will need to be started 1 month of surgery and should be continued for 1 year from start of diet. Patients in control group will not have any dietary advice. They will be followed up or 1 year. All patients who undergo surgery for Crohns disease are routinely followed up in clinic every 3 months. They also undergo

colonoscopy at 1 year. Data for the research will be collected during these clinic visits and no additional visits or procedures will be necessary. The data required for this research is predominantly collected from routine pre operative and post operative assessments done for all patients who undergo surgery for Crohns disease. Blood tests and BMI are checked routinely pre operatively and on follow ups. For purpose of research, an additional 10 ml of blood is collected for measuring IgG4 titres, at recruitment and every 3 months during follow ups. Information about patients relevant symptoms over the previous 24 hrs will also be collected pre operatively and on follow ups using a questionnaire. Mesenteric (part of intestine) samples collected will either be blood spilt during the procedure or collected from mesenteric veins which will be resected. This will add less than 5 minutes to the operative procedure.

What are the possible benefits and risks of participating?
We do not envisage any side effects. Dietary advice will be provided if necessary. Patients may be made aware of food hypersensitivities. As a result of blood testing dietary changes may be suggested to you, we hope to bring about symptomatic improvement and less frequent relapses. Patients will be provided with contact details for the research team to be contacted in reasonable hours for any clarifications.

Where is the study run from?
St George's Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2013 to April 2015

Who is funding the study?
St George's Hospital (UK)

Who is the main contact?
Felix Nicholas
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number

Version 11.2

Study information

Scientific Title
Preventing postoperative relapse of Crohn's disease by using IgG4 guided exclusion diets: A randomised controlled trial

Study objectives
Exclusion of specific food types in diet determined by serum IgG4 levels helps prevent relapse in patients who undergo surgery for Crohn's disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Crohn's disease

Interventions
This will be a randomised controlled study. Patients will be enrolled for the study preoperatively. Patients will be invited to participate at the first available opportunity following the decision to perform surgery. The discussion could be held in the hospital wards in case of urgent surgeries and outpatient clinics for those undergoing elective procedure. Results from routine pre operative checks including BMI, CRP levels, Hemoglobin level, WBC count, platelet count, prealbumin, Albumin levels and faecal calprotectin levels will be collected. An additional 10 ml of blood will be collected at the same venepuncture for IgG4 titers. The sample will be centrifuged and stored at -40o C and processed in batches of four. IgG4 levels against 14 common food antigens will be checked using fluoroenzymeimmunoassay. Modified CDAI questionnaire will also be completed at enrolment. They will be randomized into intervention group and control (normal diet) group by simple randomization.

Four food antigens (and hence food types) against which each patient had the highest titres will be identified. Patients in the intervention group will be apprised of the IgG4 titres prior to discharge and appropriate written advice on food to be excluded will be given. Exclusion diet will be commenced 1 month after surgery. Patients in control group will continue to have normal diet. No changes to their drug maintenance regimen will be made.

As a routine, all postoperative patients with Crohn's disease are followed up in the clinic every 3 months. On each routine follow up, they undergo clinical examination including BMI and laboratory tests. Laboratory tests include Hemoglobin levels, WBC count, platelet count, albumin levels, pre albumin levels, CRP levels, liver function tests, renal function tests and faecal calprotectin levels. In addition, they undergo colonoscopy at one year. For the purpose of the study, results from the routine assessments including BMI, Hemoglobin, CRP levels, Platelet, WBC count, Albumin levels and faecal calprotectin will be collected on each follow up for 1 year (4 visits). Modified CDAI questionnaire will also be completed at each visit. A further 10 ml of blood will be collected for IgG4 titres on each visit. Their compliance to diet will be confirmed. Our team will perform majority of the colonoscopies for patients included in the study and Rutgeerts score will be recorded. In such cases where patients in our study are booked into a different endoscopy list, the appropriate endoscopist will be contacted prior to the procedure and apprised of this study. A member of the research team will be present personally during the procedure to ensure Rutgeerts score is recorded

In summary, patients in intervention group will be advised to exclude four food types for period of 1 year. Their follow up is similar to that of all patients following surgery for Crohn's disease irrespective of participation in the study. We will collect additional 10 ml of blood at recruitment and 4 follow up visits.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Relapse over a 1 year period defined by Rutgeerts endoscopic severity score of i2, i3 or i4
2. Crohn's Disease Activity Index (CDAI) >150 or CDAI increase of more than 100 over baseline
3. Need for therapy to induce remission

Key secondary outcome(s))
Improvement in quality of life, measured by Short Inflammatory Bowel Disease Questionnaire (SIBDQ)

Completion date
01/03/2015

Eligibility

Key inclusion criteria
1. Patients with histological diagnosis of Crohn's disease
2. Patients who needed surgery for Crohn's disease
3. Patients who agreed to dietary therapy for a minimum of 1 year or until relapse
4. Patients aged 16 and over
5. Patients capable of providing informed consent

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
16 years

Sex
All

Key exclusion criteria
1. Severe disease unrelated to Crohn's disease like chronic renal failure or chronic liver disease or immunological disorders
2. Disease localised perineum
3. Other inflammatory conditions of bowel including Ulcerative colitis

Date of first enrolment
01/03/2013

Date of final enrolment
01/03/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St George's Hospital
London
United Kingdom
SW17 0QT

Sponsor information

Organisation
St George's University of London (UK)

ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Colorectal Research Fund at St George's Hospital (UK)

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes