ISRCTN44563171 https://doi.org/10.1186/ISRCTN44563171

Pilot study to assess mucosa-associated microflora changes induced by defined formula diet and other therapies in inflammatory bowel diseases

Submission date 29/09/2006	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 29/09/2006	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 30/01/2015	**Condition category** Digestive System	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Miss Tanya Gilliver

Contact details
Department of Nutrition and Dietetics
Hammersmith
Hammersmith Hospital
Du Cane Road
London
United Kingdom
W12 0HS

Additional identifiers

Protocol serial number
N0016165995

Study information

Scientific Title
Pilot study to assess mucosa-associated microflora changes induced by defined formula diet and other therapies in inflammatory bowel diseases

Study objectives
It is now well established that the gut microflora plays a key role in the cause and / or sustaining of inflammation in Crohn's disease and ulcerative colitis. The main objective of this study is to identify (quantify and qualify) any changes in the gut microflora caused by various treatments, especially defined formula diets.

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)
Treatment

Health condition(s) or problem(s) studied
Digestive System: Crohn's disease

Interventions
This is an open, randomised study to assess the qualitative and quantitative changes of the mucosa-associated flora in patients with Crohn's disease on different treatments for their active disease. Patients will be recruited voluntarily, with informed consent from in patients on the wards and out patient clinics. Treatment with elemental diet is a primary therapy in Crohn's disease and leads to mucosal healing during treatment. Steroid treatment induces remission but does not have the same effect on mucosal healing. Infliximab treatment is well known to induce mucosal healing rapidly and with a high rate of efficacy. Therefore we have chosen Infliximab treated patients as our control group, to determine the changes in microflora that might occur as a consequence of mucosal healing alone. This will serve as a comparator to the flora changes due to elemental diet therapy.

Patients will be assigned to treatment with Infliximab through normal clinical management decisions and these patients will act as the control group.
Patient who would normally be treated with elemental diet will then be randomised to either elemental diet treatment (EO28 commercially available product from SHS) or elemental diet treatment plus 12g fructan-oligofructose.

Updated 30/01/2015: the trial was stopped in September 2007 due to recruitment difficulties.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Infliximab, fructan-oligofructose

Primary outcome(s)
Changes in gut microflora before and after treatment

Key secondary outcome(s))
Not provided at time of registration

Completion date
30/06/2008

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
30/06/2005

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hammersmith Hospital
London
United Kingdom
W12 0HS

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hammersmith Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration