

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/01/2015	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

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

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 measure

Changes in gut microflora before and after treatment

Secondary outcome measures

Not provided at time of registration

Overall study start date

30/06/2005

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

Age group

Adult

Sex

Not Specified

Target number of participants

30 patients with Crohn's disease and 10 with ulcerative colitis

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**

England

United Kingdom

Study participating centre

Hammersmith Hospital

London

United Kingdom

W12 0HS

Sponsor information**Organisation**

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

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hammersmith Hospital NHS 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