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Dietary Microparticles in the Aetiology and Treatment of Crohn's Disease

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 08/12/2008	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Miss Miranda Lomer

Contact details
St Thomas' Hospital
Nutrition and Dietetic Department
St Thomas' Hospital
London
United Kingdom
SE1 7EH
+44 020 7928 9292 Extn 2342

Additional identifiers

Protocol serial number
REC00114

Study information

Scientific Title

Study objectives

Does the removal of modern Western inorganic microparticles from the diet of patients with Crohn's disease improve their symptoms? The aims of the project are:
1. To characterise the undegradeable inorganic microparticulate matter of the modern Western diet
2. To compare the nutrient and microparticle intake in Crohn's disease versus controls
3. To undertake a multi-centre dietary intervention study of microparticle exclusion in 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)
Not Specified

Health condition(s) or problem(s) studied
Digestive system diseases: Inflammatory bowel disease

Interventions
Not provided at time of registration

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Changes in Crohn's disease activity using the Harvey Bradshaw index (HBI) and the CDAI at four weekly appointments with the clinician and research nurse
2. Changes in use of medication will also be investigated.

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

Completion date
31/12/2001

Eligibility

Key inclusion criteria

Crohn's disease patients, cohabiting fit family members, non-Crohn's disease patients and age /sex matched controls (n=50/group) will be interviewed from the gastrointestinal clinics and staff at St Thomas' hospital.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
31/12/1998

Date of final enrolment
31/12/2001

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St Thomas' Hospital
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS Executive London (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?
Results article	results	01/03/2005		Yes	No