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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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure

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.

Secondary outcome measures
Not provided at time of registration

Overall study start date
31/12/1998

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
100

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
England

United Kingdom

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

Sponsor information

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

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.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive London (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2005		Yes	No