

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

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/12/2008	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

**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 undegradable 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?
<a href="#">Results article</a>	results	01/03/2005		Yes	No