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The value of faecal calprotectin (CPT) in monitoring the response to treatment of patients with inflammatory bowel disease

Submission date 12/09/2003	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Stopped	
Last Edited 28/04/2015	**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
N0544122068

Study information

Scientific Title
The value of faecal calprotectin (CPT) in monitoring the response to treatment of patients with inflammatory bowel disease

Study objectives
Do patients whose treatment, leading to symptomatic improvement, results in a fall of faecal calprotectin (CPT) to less than 250 µg/g have longer remissions than those whose CPT after treatment remains elevated?

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

Health condition(s) or problem(s) studied
Inflammatory bowel disease

Interventions
Patients with active inflammatory bowel disease will be treated for 2 weeks according to the advice of their clinicians with either oral prednisolone 40 mg daily (ulcerative colitis or Crohn's) or enteral feeds (Crohn's disease only). Patients failing to respond clinically to the initial 2 weeks treatment will be excluded from the trial. Those who reach remission will provide a faecal specimen for analysis of CPT. If this is less than 250 µg/g they will proceed with standard continuing therapy, either tailing off the corticosteroids, or continuing with food reintroductions if on an enteral feed. Those whose CPT after 2 weeks treatment is still raised, despite clinical improvement, will be randomised either to follow corticosteroid reduction or food reintroduction as before, or alternatively to continue the original treatment of prednisolone 40

mg, or enteral feed, with weekly determinations of CPT until the CPT falls below 250 µg/g or 4 weeks have elapsed, whichever is the sooner. Patients will be followed up for 6 months with monthly determinations of faecal CPT; clinical relapse rates in those whose CPTs after the initial 2 weeks treatment were greater, or less, than 250 µg/g will be compared.

Updated 28/04/2015: the trial was stopped due to participant recruitment issues.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
17/01/2003

Completion date
16/01/2006

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
80 patients

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
80

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
17/01/2003

Date of final enrolment
16/01/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrooke's NHS Trust
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (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