

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
Registration date 12/09/2003	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 28/04/2015	Condition category Digestive System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

16/01/2006

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

80 patients

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

17/01/2003

Date of final enrolment

16/01/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Addenbrooke's NHS Trust
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration