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Randomized controlled trial to compare stapled functional end to end anastomosis against sutured end to end anastomosis following ileocolonic resection for terminal ileal Crohn's disease or recurrence of Crohn's disease in the terminal ileum

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 21/02/2012	**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
N0265041723

Study information

Scientific Title

Study objectives
Whether a wider stapled anastomosis is associated with a lower recurrence rate than a sutured end to end anastomosis.

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)
Hospital

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Digestive System: Crohn's disease

Interventions
Prospective randomized trial to compare stapled "functional end to end anastomosis" (side to side in reality) with sutured end to end anastomosis in patients having:
a. Resection of ileocaecal Crohn's disease
b. Resection of recurrent ileocaecal Crohn's disease.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Lower recurrence rate.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2000

Completion date
01/01/2008

Eligibility

Key inclusion criteria
Patients with ileocolonic Crohn's disease needing a resection.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2000

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
GI Surgery
Birmingham
United Kingdom
B15 2TH

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
University Hospital Birmingham NHS Trust (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	01/07/1999		Yes	No