

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	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/02/2012	Condition category Digestive System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

Protocol serial number
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

Study type(s)

Not Specified

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(s)

Lower recurrence rate.

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/01/2008

Eligibility

Key inclusion criteria

Patients with ileocolonic Crohn's disease needing a resection.

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

01/01/2000

Date of final enrolment

01/01/2008

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

GI Surgery

Birmingham

United Kingdom

B15 2TH

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

University Hospital Birmingham NHS Trust (UK)

Results and Publications

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