

# 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

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	
<b>Last Edited</b> 21/02/2012	<b>Condition category</b> Digestive System	

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr MRB Keighley

**Contact details**  
GI Surgery  
Queen Elizabeth Hospital  
Birmingham  
United Kingdom  
B15 2TH

## 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?
<a href="#">Results article</a>	results	01/07/1999		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes