

# 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
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/02/2012	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

**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

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?
<a href="#">Results article</a>	results	01/07/1999		Yes	No