

A randomised controlled trial comparing stapled to sutured side to side anastomosis in Crohn's 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 20/10/2010	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

Contact name

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Additional identifiers

Protocol serial number

N0515071873

Study information

Scientific Title

Study objectives

1. Comparing side to side anastomosis in Crohn's disease, sutured versus stapled.
2. Looking at recurrence rates endoscopically, clinically and reoperation rates.

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)

Not Specified

Health condition(s) or problem(s) studied

Digestive System: Crohn's disease

Interventions

Randomised to either sutured or stapled side to side anastomosis following resection for Crohn's disease. Colonoscopy at 6 months, 1 year, 3 years and 10 years, plus clinical follow up.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Endoscopic assessment, symptomatic and reoperation rates.

Key secondary outcome(s)

Not provided at time of registration

Completion date

06/03/2010

Reason abandoned (if study stopped)

Lack of staff/facilities/resources

Eligibility

Key inclusion criteria

Assuming a 30% decrease in recurrence for the stapled group, we would hope to recruit 50 patients per group. All over 16 years of age.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

06/03/2000

Date of final enrolment

06/03/2010

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Department of General Surgery

Harrow, Middlesex

United Kingdom

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Sponsor information**Organisation**

Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
North West London Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration