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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 [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Stopped	
Last Edited 20/10/2010	**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
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Interventions
Randomised to either sutured or stapled side to side anastamosis 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 measure
Endoscopic assessment, symptomatic and reoperation rates.

Secondary outcome measures
Not provided at time of registration

Overall study start date
06/03/2000

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

Age group
Adult

Sex
Not Specified

Target number of participants
100

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
England

United Kingdom

Study participating centre

Department of General Surgery
Harrow, Middlesex
United Kingdom
HA1 3UJ

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
North West London Hospitals 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