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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

Contact name
Mr Alastair Windsor

Contact details
Department of General Surgery
North West London Hospitals NHS Trust
Northwick Park Hospital
Watford Road
Harrow, Middlesex
United Kingdom
HA1 3UJ
+44 0181 864 3232
alwindsor@aol.com

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

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
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(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
HA1 3UJ

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