ISRCTN73474172 https://doi.org/10.1186/ISRCTN73474172

Do side to side stapled anastomosis reduce the rate of perianastomotic recurrence in Crohn's Disease? A single-blinded prospective randomised trial

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
12/09/2003	Completed	[_] Results
Last Edited	Condition category	[_] Individual participant data
18/07/2014	Digestive System	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0547102225

Study information

Scientific Title

Study objectives
Do side to side stapled anastomosis reduce the rate of peri-anastomotic recurrence rate following a resection for Crohn's disease as this technique results in a wider anastomotic lumen and less tissue ischaemia at the anastomotic site?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-blinded randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Patients are randomised to side to side stapled anastomosis, or end to end sutured anastomosis, both of which are current practice.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
31/07/2001

Completion date
31/07/2011

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
30-50 local patients

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
31/07/2001

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Consultant Surgeon and Coloproctologist
Norwich
United Kingdom
NR1 3SR

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
East Norfolk and Waveney Research Consortium - Norfolk and Norwich University (UK) Hospital /Norwich PCT

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