

Stapled side-to-side anastomosis versus sutured end-to-end anastomosis following resection for primary or recurrent Crohn's disease

Submission date 09/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/08/2009	Condition category 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MCT-50012

Study information

Scientific Title

Multicentre randomised controlled trial to compare stapled side-to-side anastomosis with sutured end-to-end anastomosis following resection for primary or recurrent Crohn's disease

Acronym

CAST (The Canadian and American Surgical Crohn's Disease Trial)

Study objectives

Patients having an ileocolonic resection for Crohns Disease will have a lower risk of recurrent disease if they have a wide side-to-side anastomosis compared to a end-to-end anastomosis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Mount Sinai Hospital Research Ethics Board approved on the 28th November 2000

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Crohns disease

Interventions

Group 1: Hand sewn anastomosis

Group 2: Stapled anastomosis

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Severe endoscopic recurrence at one year follow-up.

Secondary outcome measures

1. Symptomatic recurrence (up to 24 months after)
2. Post-operative complication rates
3. Operative times

Overall study start date

01/01/2002

Completion date

31/07/2005

Eligibility

Key inclusion criteria

1. Women and men aged greater than 16 years
2. Elective ileocolonic resection
3. Colonoscopy and Small Bowel Endoscopy (SBE) completed within the last 3 years
4. Crohns Disease involving the terminal ileum plus or minus right colonic disease
5. No other sites of involvement with Crohns disease in the Gastrointestinal (GI) tract current or past
6. Willing to return for colonoscopy at 12 months

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

200

Key exclusion criteria

1. Require emergency surgery
2. Have sites of Crohns involvement elsewhere, except for minimal perianal disease
3. Have had strictureplasties or other resections for Crohns disease performed either at this operation or previously, the exception being resections for fistula disease in bowel not affected by Crohns disease
4. Require a bypass procedure or defunctioning ileostomy during the index procedure
5. Have compromised renal function (serum creatinine level greater than 130 mmol/l or 1.5 mg/l)
6. Prednisone, budesonide, 5-Aminosalicylic Acid (5-ASA) medications, ciprofloxacin,

metronidazole, cyclosporin and Anti-Tumour Necrotising Factor (Anti-TNF) and any other medications used to treat Crohns cannot be discontinued postoperatively
7. Are unable or willing to give informed consent and return for a colonoscopy at 12 months

Date of first enrolment

01/01/2002

Date of final enrolment

31/07/2005

Locations

Countries of recruitment

Canada

Study participating centre**Mount Sinai Hospital**

Toronto

Canada

M5G 1X5

Sponsor information

Organisation

Mount Sinai Hospital (Toronto) (Canada)

Sponsor details

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Sponsor type

Not defined

ROR

<https://ror.org/05deks119>

Funder(s)

Funder type

Charity

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-50012)

Funder Name

Crohns & Colitis Foundation of America (USA)

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?
Results article	results	01/05/2009		Yes	No