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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/09/2005	**Overall study status** Completed	
Last Edited 04/08/2009	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Robin Susan McLeod

Contact details
Mount Sinai Hospital
449-600 University Avenue
Toronto
Canada
M5G 1X5
+1 416-586-8534
rmcleod@mtsinai.on.ca

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 with 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
600 University Avenue
Toronto
Canada
M5G 1X5
+1 416-586-8348
mmckenzie@mtsinai.on.ca

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