Optimising surgical anastomosis in ileocolic resection for Crohn's disease to reduce recurrent disease: A Randomized controlled trial comparing hand-sewn (END-TO-END or Kono-S) to stapled anastomosis (END2END study)

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To understand if handsewn (end to end and Kono S side to side) anastomoses is superior to side to side stapled anastomosis after ileocolic resection for Crohn's disease with respect to endoscopic recurrence, gastrointestinal function and costs...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON56161

Source
ToetsingOnline

Brief title
END2END study

Condition

- Gastrointestinal inflammatory conditions
- Gastrointestinal therapeutic procedures

Synonym
Recurrent Crohn's disease, return of Crohn's disease

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Anastomosis, Crohn's disease, Ileocolic resection

Outcome measures

Primary outcome

• Endoscopic recurrence at six months following ileocolic resection defined as

SES-CD of the terminal ileum >2 and Rutgeerts >i2b by central reading.

Primary Objective: Recurrence at six months following ileocolic resection

defined as Rutgeerts

>i2b assessed by local and central reading separately for comparison blinded

for the type of anastomoses. The quality of endoscopic scoring and over scoring

will be assessed comparing local scoring by the treating gastroenterologist and

the central reading scoring for the different types of anastomoses.

Secondary outcome

Secondary Objectives:

• Post-operative 30 days complications

• Histologic and clinical recurrence at 6 months

• Clinical recurrence within 1 year

• Need for restarting immunosuppressive medication within the first year

postoperatively for endoscopic or clinical recurrence.

• QOL as measured by EuroQol, IBDQ and SF-36 at baseline and at 6 months

• Health care consumption and costs of readmission, outpatient clinic and

diagnostics

• The 5 year reoperation rate for recurrence of disease at the anastomotic

site.

Study description

Background summary

Half of the surgeries for intestinal Crohn*s disease comprises of (re)resection of the (neo)terminal ileum. Unfortunately, surgery for CD is not curative, and disease recurrence is common with up to 60% having endoscopic recurrence at six months. According to the ECCO guidelines endoscopic assessment of recurrence is advised 6 months after surgery and scored with the modified Rutgeerts classification. The scoring has prognostic implications, is used to restart medical therapy and is a common endpoint in trials. Wound healing of inverted stapled anastomosis is essentially different from handsewn anastomosis and is associated with ulcerations at the staple line leading to systematic over scoring of Crohn's recurrence. The patient is unjustly diagnosed with disease recurrence leading to unnecessary restarting of expensive drugs compromising the QOL and increasing costs. In addition, the side-to-side configuration might cause stasis which fuels recurrence and gastrointestinal dysfunction.

Therefore we hypothesize that the end to end or kono-S handsewn anastomosis compared to the stapled side to side anastomosis shows less ulcerations at 6 months after surgery scored with the SES-CD either at the site of the anastomosis (different type of healing) and in the afferent ileum (stasis). We also hypothesize that this type of anastomosis is associated with less abdominal complaints and therefore is more sustainable.

Study objective

To understand if handsewn (end to end and Kono S side to side) anastomoses is superior to side to side stapled anastomosis after ileocolic resection for Crohn's disease with respect to endoscopic recurrence, gastrointestinal function and costs.

Study design

The study design is a Monocenter Randomized superiority trial

Intervention

The following groups will be compared:
Group 1 (intervention): Handsewn end to end anastomosis (end to end or Kono-s)
Group 2 (standard): Stapled side to side anastomosis

Study burden and risks

All patients will undergo am ileocolic resection or resection of the neoterminal ileum for Crohns disease. According to the ECCO guidelines the preferred anastomose technique is a stapled ileocolic side-to-side anastomose. However, both the handswen anastomosis and the stapled anastomos, are well-known and commonly performed standard treatment approaches that are currently used for CD or colon carcinoma. Both procedures will be performed as a laparoscopic resection with conversion to an open operation only if clinically indicated. Prior to surgery, all patients will have colonoscopy with biopsy, and a MR or CT enterography performed. Operative data and thirty-day postoperative data will be collected. At 6 months, and if clinically indicated at one year, patients will undergo colonoscopy with biopsies taken from the distal ileum and proximal colon on either side of the anastomosis to assess endoscopic and histologic recurrence. Endoscopic recurrence will be assessed by local central reading. In literature, the 6 months endoscopic recurrence rate (defined as Rutgeerts >=i2b) is estimated to be around 60%.
To detect a difference of 25% endoscopic recurrences at 6 months between the two randomized surgeries, a total number of 165 patient is needed (included lost to follow-up).

Patients will be assessed at 4 weeks, 3 months, 6 months and 12 months.The Crohn*s Disease Activity Index (CDAI) is determined at baseline visit based on seven day scoring by the patient prior to this visit. Moreover, quality of life questionnaires are administered at baseline and each visit: EuroQol, a five dimensions questionnaire (EQ-5D), 36-Item Short Form Health Survey (SF-36), and Inflammatory Bowel Disease Questionnaire (IBDQ).The iMCQ and iPCQ questionnaires are administered at 3 months, 6 months and 12 months postoperatively as part of the economic evaluation of the different surgical interventions.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Males and females aged >16 years
2. Ileocolic disease or disease of the neoterminal ileum with an indication for resection
3. Concurrent therapies with corticosteroids, 5-ASA drugs, thiopurines, MTX, antibiotics, and anti-TNF therapy are permitted.
4. All patients should have ileocolic disease or disease of the neoterminal ileum previously confirmed during endoscopy, with a recent update of imaging (e.g. Ultrasound, MR enterography (or CT enterography if MR is contraindicated))
5. Ability to comply with protocol.
6. Competent and able to provide written informed consent.

7. Patiënt must have been discussed in the local MDT

Exclusion criteria

1. Inability to give informed consent.
2. patients less than 16 years of age.
3. Clinically significant medical conditions within the six months before the operation : e.g. myocardial infarction, active angina, congestive heart failure or other conditions that would, in the opinion of the investigators, compromise the safety of the patient.
4. History of cancer < 5 years which might influence patients prognosis
5. Emergent operation.
6. Pregnant or breast feeding.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-07-2023
Enrollment:	165
Type:	Actual

Ethics review

Approved WMO

Date:	27-09-2022

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-08-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-12-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-05-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-01-2025
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05578235
CCMO	NL81981.018.22