# Influence of latero-lateral versus end-to-end ileo-ascendostomy on recurrence and complications after ileocaecal resection in patients with Crohn's disease

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>			
14/08/2008		☐ Protocol			
Registration date	Overall study status	Statistical analysis plan			
09/10/2008	Completed	[X] Results			
Last Edited	Condition category	[] Individual participant data			
01/02/2012	Digestive System				

### Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

### Contact name

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# Additional identifiers

### Protocol serial number

N/A

# Study information

### Scientific Title

### **Acronym**

LATEND trial

### Study objectives

An important problem after surgical resection of Crohn's disease remains the high risk of recurrence. The anastomosis region is the most common localisation for recurrence and may lead to prompt reoperation. The configuration of the anastomosis is an often discussed reason for this phenomena. Wide stapled latero-lateral anastomoses appear to provide fewer relapses due to a reduced risk of re-stenosis than conventional sutured end-to-end-anastomosis, on the other hand there seems to be an increased risk of fistulas after stapled anastomosis. The existing literature on this topic has several essential deficits thus reducing their validity.

Therefore a randomised controlled multicentre trial under standardised conditions is necessary to achieve a high validity to investigate the influence of latero-lateral versus end-to-end ileo-ascendostomy on recurrence and complications after ileocaecal resection in patients with Crohn's disease.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Local Medical Ethics Committee gave approval on the 20th October 2005

### Study design

Multicentre randomised controlled trial

## Primary study design

Interventional

# Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Crohn's disease

### Interventions

Group one: ileocaecal resection with conventional sutured end-to-end ileo-ascendostomy Group two: ileocaecal resection with stapled latero-lateral ileo-ascendostomy

The total duration of follow-up for both treatment arms is 3 years.

### Intervention Type

Other

### **Phase**

### Primary outcome(s)

Endoscopic proven perianastomotic relapse of bowel inflammation one year after surgical resection (using an endoscopic relapse score).

### Key secondary outcome(s))

- 1. Endoscopic proven perianastomotic relapse of bowel inflammation three years after surgical resection (using an endoscopic relapse score): one and three years after randomisation
- 2. Symptomatic perianastomotic relapse (diarrhoea, pain, fever, weight reduction, increasing inflammation parameters in blood): one and three years after randomisation
- 3. Relapse with indication for surgical resection: one and three years after randomisation
- 4. Anastomotic leaks: day of discharge from the hospital

### Completion date

31/10/2009

# Eligibility

### Key inclusion criteria

- 1. Aged greater than or equal to 18 years, either sex
- 2. Ileal stenosis or stricture due to Crohn's disease with indication for ileocaecal resection or right hemicolectomy
- 3. First perianastomotic relapse of bowel inflammation with indication for surgical resection

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

All

### Key exclusion criteria

- 1. Other intestinal inflammation due to Crohn's disease
- 2. Aged less than 18 years
- 3. Pregnancy
- 4. Given or assumed indication for post-operative medication with azathioprine
- 5. Impossibility of post-operative dose reduction for cortisone medication

### Date of first enrolment

01/02/2006

# Date of final enrolment

31/10/2009

# Locations

### Countries of recruitment

Germany

Study participating centre Charite - Universitatsmedizin Berlin Berlin Germany 12200

# Sponsor information

### Organisation

Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

### **ROR**

https://ror.org/001w7jn25

# Funder(s)

### Funder type

Hospital/treatment centre

### **Funder Name**

Charite - University Medicine Berlin (Charite - Universitatsmedizin Berlin) (Germany) - Department of General, Vascular and Thoracic Surgery, Campus Benjamin Franklin

### **Funder Name**

GAST-study group (Germany)

# **Results and Publications**

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**Not provided at time of registration

# Study outputs

occurs occurs					
Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes