

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Heinz J. Buhr

Contact details
Charite - Universitätsmedizin Berlin
Campus Benjamin Franklin
Department of General, Vascular and Thoracic Surgery
Hindenburgdamm 30
Berlin
Germany
12200
+49 (0)30 8445 2543
heinz.buhr@charite.de

Additional identifiers

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

Primary study design

Interventional

Study design

Multicentre randomised controlled trial

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

Not Specified

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 - Universitätsmedizin 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 - Universitätsmedizin 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

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2013		Yes	No