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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/10/2008	**Overall study status** Completed	
Last Edited 01/02/2012	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/02/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
224

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)

Sponsor details
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Sponsor type
University/education

Website
http://www.charite.de/

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

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	01/03/2013		Yes	No