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Prospective, randomised, multicentre trial to assess short- and long-term results after laparoscopic and conventional resection of colorectal carcinoma

Submission date 15/07/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 31/07/2008	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 31/07/2008	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

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
01091998

Study information

Scientific Title

Acronym
Lapkon II study

Study objectives
Null hypothesis: The hypothesis of the randomised, controlled, multicentre study Lapkon II was that the rate of recurrence after five years is not higher after laparoscopic compared to conventional resection of colonic and upper rectal cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central Ethical Committee of Charité - University Medicine Berlin. Date of approval: 24/07/1998 (ref: 565/96)

Study design
Randomised, controlled, multicentre study

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
Colonic and upper rectal cancer

Interventions
Laparoscopic vs conventional resection of colorectal carcinoma

After initial diagnostic laparoscopy, the result of the randomisation was intraoperatively revealed and the resection was carried out with either the laparoscopic or open technique.

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Cancer-free survival 5 years after surgery

Secondary outcome measures
1. Short-term overall, general and local morbidity
2. Intraoperative complications
3. Duration of surgery
4. Length of the specimen
5. Number of lymphnodes removed
6. Status of resection margins
7. Postoperative hospital stay

Overall study start date
01/09/1998

Completion date
30/09/2004

Eligibility

Key inclusion criteria
1. Both males and females
2. Tumour located in the upper rectum (above 12 cm from the anal verge) or the colon
3. Scheduled for right hemicolectomy, sigmoidectomy, or anterior rectal resection

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1,200

Key exclusion criteria
1. Adenocarcinoma of the transverse colon or the colonic flexures necessitating extended left or right 2. Hemicolectomy or subtotal colectomy
3. Distant metastasis (i.e. liver or lung)
4. Contraindications to pneumoperitoneum
5. Acute intestinal obstruction
6. Perforation
7. Abscess

8. Malignant disease in the past 5 years (excluding skin basiloma or carcinoma in situ of the cervix)
9. Synchronous adenocarcinoma of the colorectum
10. Pregnancy
11. Age below 18 years
12. Unwilling to consent

Date of first enrolment
01/09/1998

Date of final enrolment
30/09/2004

Locations

Countries of recruitment
Germany

Study participating centre
General, Visceral, Vascular and Thoracic Surgery
Berlin
Germany
10117

Sponsor information

Organisation
Charité - University Medicine Berlin (Germany)

Sponsor details
Charitéplatz 1
Berlin
Germany
10117

Sponsor type
University/education

Website
http://www.charite.de/en/charite/

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Participating hospitals will cover their costs for this trial. The lead hospital is Charité Campus Mitte - University Medicine Berlin (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