

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

Submission date

15/07/2008

Registration date

31/07/2008

Last Edited

31/07/2008

Recruitment status

No longer recruiting

Overall study status

Completed

Condition category

Cancer



Retrospectively registered



Protocol not yet added



SAP not yet added



Results not yet added and study completed for more than 2 years



Raw data not yet added



Study completed

Plain English Summary

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

General, Visceral, Vascular and Thoracic Surgery

Charité - University Medicine Berlin

Campus Mitte

Charitéplatz 1

Berlin

Germany

10117

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number

01091998

Study information

Scientific Title

Acronym

Lapkon II study

Study hypothesis

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

Condition

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

Overall study end date

30/09/2004

Eligibility**Participant 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

Participant 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

Recruitment start date

01/09/1998

Recruitment end date

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