

Influence of intraperitoneal application of taurolidine on the perioperative metastases, tumor recurrence and survival rate after surgical resection of colorectal cancer

Submission date 15/03/2005	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 05/05/2005	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 06/02/2008	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

Study information

Scientific Title

Acronym
IPAT-MET

Study objectives

Recurrence rates after colon resection for cancer are 16% to 18% (Surgical Therapy Study Group). The study hypothesis is that the intraoperative intraperitoneal lavage with taurolidine reduces the 5-year recurrence rate from 16% to 10%.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Colorectal cancer

Interventions

2000 patients with colorectal cancer will be randomised to receive either taurolidine or NaCl solution during resection. Tumor recurrence, metastases and survival rates will be investigated up to 5 years.

Intraoperative instillation of 1% taurolidine versus 0.9% NaCl solution, evaluation of morbidity and mortality, side-effects, long-term follow-up after 3, 6, 12 month and 2, 3, 4 and 5 years.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Taurolidine

Primary outcome(s)

Time to local and distant tumor relapse (disease free survival).

Key secondary outcome(s)

Global survival time.

Completion date

31/12/2006

Eligibility

Key inclusion criteria

Patients with colorectal cancer and curative resection, age over 18 years, American Society of Anesthesiologists (ASA) classification <IV.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Key exclusion criteria

1. Ileus
2. Peritoneal carcinomatosis
3. Intraperitoneal abscess formation
4. Intestinal perforation
5. Peritonitis
6. Sepsis
7. Organ failure
8. ASA classification IV
9. R1 or R2 resection

Date of first enrolment

01/06/2005

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

Germany

Study participating centre

Charité - University Medicine Berlin
Berlin

Germany
10117

Sponsor information

Organisation

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

ROR

<https://ror.org/001w7jn25>

Funder(s)

Funder type

Industry

Funder Name

Funding of the Insurance (Gehrling-Konzern) Vers.Nr.: 70-5644584-4 by Böhringer Ingelheim (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration