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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 05/05/2005	**Overall study status** Completed	
Last Edited 06/02/2008	**Condition category** Cancer	

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
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

Study design
Randomised controlled trial

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

Secondary outcome measures
Global survival time.

Overall study start date
01/06/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
2000

Key exclusion criteria
1. Ileus
2. Peritoneal carcinomatosis
3. Intraperitoneal abscess formation
4. Intestinal perforation
5. Peritonitis
6. Sepsis
7. Organ falure

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)

Sponsor details
Department of Surgery
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Sponsor type
University/education

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

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