ISRCTN66478538 https://doi.org/10.1186/ISRCTN66478538

Intra-operative administration of taurolidine reduces level of interleukin-1 beta rather than povidone-iodine in patients with colon, gastric, and pancreatic cancer. A clinical prospective randomised multicenter trial.

Submission date
12/09/2005

Recruitment status
No longer recruiting

Registration date
17/02/2006

Overall study status
Completed

Last Edited
23/07/2009

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Chris Braumann

Contact details
Schumannstrasse 20/21
Berlin
Germany
10117
+49 (0)30450622156
chris.braumann@charite.de

Additional identifiers

Study information

Scientific Title

Acronym
IPATI

Study objectives
Taurolidine suppresses the intraperitoneal levels of cytokines and might influence tumor growth

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the Charite Campus Mitte, University Hospital, (Universitaetsmedizin) Berlin, Germany, as the leading study center, approved the study design in 1998. The study was carried out in accordance with the Declaration of Helsinki. Written informed consent was obtained from all patients before enrolment.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Colon, gastric or pancreatic cancer

Interventions
120 Patients with colon, gastric or pancreatic cancer have been randomised between January 1999 and August 2001 to receive either taurolidine or povidone-iodine intraperitoneally during open resection.
Intra-operative instillation of 0.5% taurolidine versus 0.25% povidone-iodine solution.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Taurolidine, Povidone-iodine

Primary outcome(s)
Interleukin-1 beta perioperatively measured six times

Key secondary outcome(s)
1. Evaluation of morbidity and mortality
2. Side-effects
3. Long-term follow-up after 3, 6, 12 months and 2, 3, 4 and 5 years

Completion date
30/04/2005

Eligibility

Key inclusion criteria
1. Open resection of colon, gastric, or pancreatic cancer
2. American Society of Anesthesiologists (ASA) I-III classification
3. Histopathological R0-resection

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Complete ileus
2. ASA IV classification
3. Histopathological R1- or R2-resection
4. Unknown intra-operative metastasis, peritoneal carcinomatosis, intra-abdominal abscess, sepsis or clinically relevant organ failure
5. Apparent coagulopathy

Date of first enrolment
01/01/1999

Date of final enrolment
30/04/2005

Locations

Countries of recruitment
Germany

Study participating centre
Schumannstrasse 20/21
Berlin
Germany
10117

Sponsor information

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

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Other

Funder Name
Insurance funding (Gerling Versicherungs-Service AG) (Germany)

Results and Publications

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	23/03/2009		Yes	No