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.

## Study design
Randomised controlled trial

## Primary study design
Interventional

## 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 |