

# 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.

<b>Submission date</b> 12/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/02/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/07/2009	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**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

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

Interleukin-1 beta perioperatively measured six times

**Secondary outcome measures**

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

**Overall study start date**

01/01/1999

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

120

**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

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## Sponsor information

**Organisation**

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

**Sponsor details**

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**Sponsor type**

University/education

**ROR**

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

## Funder(s)

**Funder type**

Other

**Funder Name**

Insurance funding (Gerling Versicherungs-Service AG) (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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	23/03/2009		Yes	No