ISRCTN60734227 https://doi.org/10.1186/ISRCTN60734227

# Postsurgical pain Outcome of Vertical And Transverse abdominal Incision: a randomised controlled equivalent Trial

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| **Submission date**<br>29/07/2003 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>16/10/2003 | **Overall study status**<br>Completed | |
| **Last Edited**<br>16/05/2011 | **Condition category**<br>Digestive System | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
KSC 01/2003

## Study information

**Scientific Title**

## Acronym
POVATI-Trial

## Study objectives
Patients with intra-abdominal pathologic diseases, certainly operable throughout both approaches such as: stomach, pancreas and small or large bowel. This is a randomized controlled observer and patient-blinded two-group parallel trial to answer the question if the transverse abdominal incision is equivalent to the vertical one due to the described endpoints.

## 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)
Quality of life

## Health condition(s) or problem(s) studied
Abdominal surgery

## Interventions
After randomisation either in the transverse or in the vertical (= midline) group a standardised surgical abdominal approach is performed. Further surgical procedure in the vertical as well in the transverse group follows given prespecified standards. Patients are blinded via a special wound dressing. Outcome assessors are unaware of the intervention.

## Intervention Type
Drug

## Phase
Not Specified

## Drug/device/biological/vaccine name(s)
Piritramide

## Primary outcome(s)
The primary endpoint is the abdominal pain intensity experienced by a patient, quantified with the Visual Analogue Scale (VAS), and the amount of analgesic required (piritramide [mg/h]) on the second postoperative day.

## Key secondary outcome(s)

Secondary objectives are the frequencies of early- and late-onset complications such as burst abdomen, postoperative pulmonary complications, wound infections and incisional hernias. In addition, pain is quantified according to the Pain-Sensation-Scale by Geissner, a modified McGill Pain Questionnaire, designed for studies conducted in Germany.

### Completion date
01/10/2004

## Eligibility

### Key inclusion criteria
Hospitalised patients of the Department of General-, Visceral-, Traumasurgery and Outpatient Clinic of the University of Heidelberg, Medical School, who are planned for an elective abdominal operation and are suitable for both transverse and vertical incision.

1. Age equal or greater than 18 years
2. Expected survival time more than 12 months
3. Patients scheduled for the following procedures:
a) Whipple procedure (classic or pylorus-preserving)
b) Duodenum-preserving resection of the pancreatic head
c) Gastrectomy (partial or total gastrectomy)
d) Colon resection (left or right or transverse / classic or extended)
e) Ileocecal resection
4. Primary and elective laparotomy
5. Patient must be able to give informed consent
6. Patient has given informed consent

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### Key exclusion criteria
1. Permanent therapy with a opioid equivalent drug for any reason within 12 months before operation (duration longer than 2 weeks)
2. Incompatibility of metamizole
3. Recurrent opening of the abdominal cavity (not laparoscopic appendectomy, laparoscopic cholecystectomy, laparoscopic adrenalectomy, diagnostic laparoscopy or appendectomy), including prior cesarean section and Pfannenstiel incision (e.g., hysterectomy)
4. Participation in another intervention trial that would interfere with the intervention and

outcome of this study
5. Severe psychiatric or neurologic diseases
6. Lack of compliance
7. Drug and/or alcohol abuse according to local standards
8. Current immunosuppressive therapy (more than 40 mg of a corticoid per day or azathioprine)
9. Chemotherapy within 2 weeks before operation
10. Radiotherapy of the abdomen completed longer than 8 weeks before operation (except for neoadjuvant therapy, e.g. for pancreatic cancer)
11. Liver, gallbladder, spleen, and rectum surgery

### Date of first enrolment
01/10/2003

### Date of final enrolment
01/10/2004

## Locations

### Countries of recruitment
Germany

### Study participating centre
**Department of Surgery**
Heidelberg
Germany
69120

## Sponsor information

### Organisation
University of Heidelberg Medical School (Germany)

### ROR
https://ror.org/038t36y30

## Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
University of Heidelberg Medical School (Germany) - Department of Surgery

# 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 | 01/06/2009 | | Yes | No |
| Results article | results | 01/10/2011 | | Yes | No |
| Protocol article | protocol | 13/11/2003 | | Yes | No |