

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

<b>Submission date</b> 29/07/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 16/10/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/05/2011	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Markus W Buechler

**Contact details**  
Department of Surgery  
University of Heidelberg Medical School  
Im Neuenheimer Feld 110  
Heidelberg  
Germany  
69120  
+49 (0)622 156 6200  
Markus\_Buechler@med.uni-heidelberg.de

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

# 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

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Quality of life

## Participant information sheet

## 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 measure**

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.

**Secondary outcome measures**

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.

**Overall study start date**

01/10/2003

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

172

**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)

## Sponsor details

Department of Surgery  
Im Neuenheimer Feld 110  
Heidelberg  
Germany  
69120  
+49 (0)622 156 6200  
Markus\_Buechler@med.uni-heidelberg.de

## Sponsor type

Hospital/treatment centre

## 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

### 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="#">Protocol article</a>	protocol	13/11/2003		Yes	No
<a href="#">Results article</a>	results	01/06/2009		Yes	No
<a href="#">Results article</a>	results	01/10/2011		Yes	No