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

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

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

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

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
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69120

Sponsor information

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