

Trial Description

Title

DISPACT: Distal Pancreatectomy - A randomized controlled trial to compare two different surgical techniques

Trial Acronym

DISPACT-Trial

URL of the trial

<http://www.DISPACT.de>

Brief Summary in Lay Language

The aim of the trial is to evaluate, which surgical technique is the best to reduce postoperative pancreatic fistula rate. Therefore two surgical techniques are compared to each other. Both techniques share the same goal: to remove the diseased tissue, the pancreatic tail. This resection can be performed either with the scalpel or with the stapler. Using the stapler, the remaining part of the pancreas will be closed with a stapler line, while the resection with the scalpel is followed by the manual suture of the remaining part of the pancreas. Both techniques are standards, that are used in many hospital to the same extend. But until today there is no evidence of the superiority of one techniques towards the other regarding the incidence of postoperative pancreatic fistula.

Brief Summary in Scientific Language

This is a multi-center, pre-operatively randomized, controlled and patient and observer blinded trial performed as a parallel group adaptive superiority design. The randomization is done stratified for centers and risk level (low/high). The patient is blinded for the technique used in order to prevent an impact on secondary endpoints.

Organizational Data

- DRKS-ID: **DRKS00000005**
- Date of Registration in DRKS: **2008/08/08**
- Date of Registration in Partner Registry or other Primary Registry: **2006/07/18**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **245/2006 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

- Primary Registry-ID: **18452029 (ISRCTN Register)**
- Partner Registry-ID: **UKF001249 (Register Klinischer Studien des Universitätsklinikums Freiburg)**
- Sponsor-ID: **DISPACT-Trial**

Health condition or Problem studied

- ICD10: **C25 - Malignant neoplasm of pancreas**
- ICD10: **K86.3 - Pseudocyst of pancreas**
- ICD10: **K86.1 - Other chronic pancreatitis**
- Other: **5-524: null**

Interventions/Observational Groups

- Arm 1: **Control group: Scalpel resectioning and manual closing of suture**
- Arm 2: **Experimental group: Resectioning and closing with stapler**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **[---]***
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Combined primary endpoint: presence of a pancreatic fistula and / or death due to any cause on day 7 postoperatively.

Secondary Outcome

Secondary endpoints: operating time, frequency of burst abdomen, wound infection, and intraabdominal fluid collection and abscess, postoperative length of hospital stay, new onset of diabetes mellitus, one-year survival.

Countries of recruitment

- **BE Belgium**
- **IT Italy**
- **NL Netherlands**
- **SI Slovenia**
- **UK United Kingdom**
- **DE Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2007/01/01**
- Target Sample Size: **450**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Age equal or above 18 years
- Expected survival time more than 12 month
- Patients with at least one of the following pathologic diseases scheduled for elective resection:
 - *Resectable malignancies of pancreatic body and/or tail
 - *Resectable chronic pancreatitis of the body and/or tail
 - *Resectable benigne tumours of the pancreas including neuroendocrine tumours
 - *Resectable pseudocyst of the pancreatic body and/or tail

Exclusion criteria

- Current immunosuppressive therapy
- Chemotherapy within 2 weeks before operation
- Radiotherapy within 8 weeks before operation
- Curative resection is not feasible
- Severe psychiatric or neurologic diseases
- Drug- and/or alcohol-abuse according to local standards
- Participation in another intervention trial with interference of intervention or outcome
- Inability to follow instructions given by the investigator or interviewer
- Expected lack of compliance
- Lack of informed consent

Addresses

■ Primary Sponsor

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■ Contact for Scientific Queries

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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URL: **http://www.bmbf.de/index.php**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2009/07/03**

Trial Publications, Results and other documents

- Paper **DISPACT trial: a randomized controlled trial to compare two different surgical techniques of DISTal PANcreaTectomy - study rationale and design. MK Diener, HP Knaebel, ST Witte, I. Rossion, M. Kieser, MW Buchler, CM Seiler and the DISPACT Trial Group.**
http://ctj.sagepub.com Clinical Trials DOI: 10.1177/ 1740774508096140 Clin Trials 2008; 5; 534
- Abstract **Efficacy of stapler versus hand-sewn closure after distal pancreatectomy (DISPACT): a randomised, controlled multicentre trial**

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** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*