

**Trial Description****Title**

**Distal Pancreatectomy - A randomised controlled trial to compare minimal-invasive distal pancreatectomy to open resection (DISPACT-2 Trial)**

**Trial Acronym**

**DISPACT 2**

**URL of the trial**

**<http://dispact.de>**

**Brief Summary in Lay Language**

**The success of an operation not only depends on the disease, but also on the damage of the surgical approach. Minimal invasive surgery reduces postoperative pain and results in improved mobility, fewer pulmonary infections and faster recovery and a better quality of life.**

**The DISPACT 2 study examines differences between open and minimal invasive distal pancreatic resection for postoperative complications, further clinical and oncological efficacy, safety, quality of life and costs. In addition, patient-relevant outcomes and oncological safety are examined. In the case of the same number of postoperative complications and given oncological safety and at the same time improved quality of life, minimal invasive resection should be offered to patients as the first choice.**

**Brief Summary in Scientific Language**

**Open distal pancreatectomy is the gold standard for surgical treatment of diseases of the pancreatic body and tail. The open abdominal approach itself with its increased surgical trauma compared to minimal invasive distal pancreatectomy is suspected to cause increased postoperative morbidity affecting both the patient and the healthcare system. A systematic review, performed by our group, showed reduced postoperative morbidity after laparoscopic versus open abdominal approaches across the whole field of abdominal surgery.**

**The minimal invasive approach with its reduced invasiveness promises reduction of postoperative pain and subsequently better mobilisation of patients and less respiratory complications leading to a quicker recovery and a shorter length of hospital stay. Therefore, in presence of the same postoperative morbidity the minimal invasive approach should be offered to patients as first choice.**

**Do you plan to share individual participant data with other researchers?**

**Yes**

**Description IPD sharing plan**

**After publication the data set will be available upon request for further research also to non-participating parties.**

## Organizational Data

- DRKS-ID: **DRKS00014011**
- Date of Registration in DRKS: **2018/03/20**
- Date of Registration in Partner Registry or other Primary Registry: [---]\*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **S-693/2017 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

## Secondary IDs

- Universal Trial Number (UTN): **U1111-1209-1592**

## Health condition or Problem studied

- ICD10: **C25.1 - Malignant neoplasm: Body of pancreas**
- ICD10: **C25.2 - Malignant neoplasm: Tail of pancreas**
- ICD10: **C25.3 - Malignant neoplasm: Pancreatic duct**
- ICD10: **C25.4 - Malignant neoplasm: Endocrine pancreas**
- ICD10: **C25.7 - Malignant neoplasm: Other parts of pancreas**
- ICD10: **K86.0 - Alcohol-induced chronic pancreatitis**
- ICD10: **K86.1 - Other chronic pancreatitis**
- ICD10: **D13.6 - Benign neoplasm: Pancreas**

## Interventions/Observational Groups

- Arm 1: **Minimal-invasive distal pancreatectomy (MIDP)**
- Arm 2: **Open distal pancreatectomy (ODP)**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*
- Allocation: **Randomized controlled trial**



Study Type: **Interventional**

Study Type Non-Interventional: [---]\*

Allocation: **Randomized controlled trial**

- Blinding: [---]\*
- Who is blinded: **assessor**
- Control: **Active control (effective treatment of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**Postoperative mortality and morbidity assessed as comprehensive complication index (CCI) 3 months after intervention.**

### Secondary Outcome

- **Operation time**
- **Intraoperative blood loss**
- **Conversion rate (minimal-invasive group)**
- **Days on ICU**
- **Pain (NRS)**
- **Mobility**
- **Length of hospital stay**
- **Time to functional recovery**
- **Pancreas-associated morbidity (pancreatic fistula, delayed gastric emptying, postoperative hemorrhage)**
- **Surgical site infection**
- **Re-intervention rate**
- **Time to return to work**
- **Quality of Life (EORTC QLQ-C30 and PAN 28 (CP))**
- **Incisional hernia rate**
- **Survival rate after 12 and 24 months**
- **R0 / R1 resection rates**
- **Lymph node count in oncological group**
- **DRG case cost**

### Countries of recruitment

- **DE Germany**



## Locations of Recruitment

- University Medical Center **Klinik für Allgemein-, Viszeral- und Transplantationschirurgie, Heidelberg**
- University Medical Center **Uniklinik RWTH Aachen Klinik für Allgemein-, Viszeral- und Transplantationschirurgie, Aachen**
- Medical Center **Ostalb-Klinikum Aalen, Chirurgische Klinik, Aalen**
- University Medical Center **Klinik und Poliklinik für Allgemein-, Viszeral-, Thorax- und Gefäßchirurgie, Bonn**
- University Medical Center **Klinik und Poliklinik für Viszeral-, Thorax- und Gefäßchirurgie, Universitätsklinikum Carl Gustav Carus Dresden, Dresden**
- University Medical Center **Klinik für Allgemein-, Viszeral- und Transplantationschirurgie, Universitätsklinikum Frankfurt der Goethe Universität, Frankfurt a.M.**
- University Medical Center **Department Chirurgie Klinik für Allgemein- und Viszeralchirurgie, Freiburg im Breisgau**
- University Medical Center **Universitätsklinik und Poliklinik für Viszerale, Gefäß- und Endokrine Chirurgie, Halle Saale**
- University Medical Center **Klinik für Allgemein-, Viszeral-, Gefäß- und Kinderchirurgie, Universitätsklinikum des Saarlandes, Homburg**
- Medical Center **Klinik für Viszeral-, Tumor-, Transplantations- und Gefäßchirurgie, Universitätsklinikum der privaten Universität Witten/Herdecke, Köln-Merheim**
- University Medical Center **Royal Liverpool University Hospital, Liverpool**
- University Medical Center **Dept. of Abdominal Surgery, University Medical Centre Ljubljana, Ljubljana**
- University Medical Center **Klinik für Chirurgie, Universitätsklinikum Schleswig-Holstein, Lübeck**
- University Medical Center **Klinik für Visceral-, Thorax- und Gefäßchirurgie, Universitätsklinikum Marburg Gießen GmbH, Marburg**
- Medical Center **Klinik für Allgemein -, Visceral -, Gefäß - und Thoraxchirurgie , Memmingen**
- University Medical Center **Klinik für Allgemein-, Viszeral- und Transplantationschirurgie, LMU , München**
- University Medical Center **Klinik und Poliklinik für Chirurgie, Klinikum Rechts der Isar TU München, München**
- University Medical Center **Klinik für Allgemein- und Viszeralchirurgie, Ulm**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/08/13**
- Target Sample Size: **294**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**



### Inclusion Criteria

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

### Additional Inclusion Criteria

- **Planned distal pancreatectomy with or without splenectomy for any indication**
- **Age  $\geq$  18 years**
- **Ability of subject to understand character and individual consequences of the clinical trial**
- **Written informed consent**

### Exclusion criteria

- **Patients scheduled for a pancreatic resection other than distal pancreatectomy**
- **Distant organ metastases or tumour infiltration of the superior mesenteric vein, superior mesenteric artery or hepatic artery**
- **Infiltration of adjacent organs**
- **CA 19-9 >1000 IU/ml**
- **ASA >3**
- **Prior major open abdominal surgery**
- **Participation in another intervention-trial with interference of intervention and outcome of this study**
- **Lack of compliance and lack of written informed consent**

### Addresses

#### ■ Primary Sponsor

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#### ■ Contact for Scientific Queries

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URL: **www.klinikum.uni-heidelberg.de/Chirurgische-Klinik.1010.0.html**

## 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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**53175 Bonn**

**Germany**

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E-mail: [---]\*

URL: **www.dfg.de**

## Status

- Recruitment Status: **Recruiting ongoing**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruiting started": [---]\*
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Reason, if Reason for Recruiting Stop "Other": [---]\*

- Study Closing (LPLV): [---]\*
- Number of Participants in Germany after Recruiting complete: [---]\*
- Total Number of Participants (all Sites worldwide) after Recruiting complete: [---]\*

## Trial Publications, Results and other documents

\* *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.*