Trial Description

Title

Distal resection of the pancreas with or without covering of the pancreatic remnant

Trial Acronym

DISCOVER

URL of the trial

[---]*

Brief Summary in Lay Language

This study is dealing with closure techniques of the pancreatic remnant after resection of the pancreatic tail in elective primary operations. We want to evaluate wether covering of the remnant with autologeous tissue can decrease the rate of postoperative pancreatic fistulas. All patients planed for this type of operation can take part in the study.

Brief Summary in Scientific Language

state of research:
In the literature, there are signs that additional coverage of the pancreatic remnant can reduce rate of postoperative pancreatic fistulas. The cumulative results of 5 trials show a rate of 16%. Comparing these results with the fistula rate of 36% which has been shown in the DISPACT-trial where no covering has been practiced, this would meen a big reduction.

aim of the study:
This trials wants to demonstrate that the additional coverage of the pancreatic remnant with falciform ligament, a jejunal loop or the stomach can reduce the rate of postoperative pancreatic fistulas.

Organizational Data

- DRKS-ID: **DRKS00000546**
- Date of Registration in DRKS: **2010/09/13**
- 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-093/2010 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1116-7988**

Health condition or Problem studied

- ICD10: **C25.2 - Malignant neoplasm: Tail of pancreas**

Interventions/Observational Groups

- Arm 1: **After resection of the pancreatic tail by scalpel, the remnant is closed by single stiches. Afterwards, it is additional covered by use of autologous serous tissue (falciform ligament, jejunal loop or stomach)**
- Arm 2: **After resection of the pancreatic tail by scalpel, the remnant is closed by single stiches. An additional coverage of the remnant is not practiced.**

Characteristics

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

Primary Outcome

postoperative pancreatic fistula on the criteria of the ISGPF (International Study Group on Pancreatic Fistula), messured by enzyme evaluations from the drainages and observation of the clinical course, folow up until postoperative day 40.

Secondary Outcome

morbidity (wound infection, intraabdominal fluid collections, delayed gastric emptying (DGE, international definition), potspancreatectomie haemorhage (PPH, internaltional definition), occurence of burst abdomen, new onset diabetes mellitus), total operation time in minutes, frequence and kind of operative and interventional revisions, mortality (death of any cause until postoperative day 7),

hospital- and intensive care stay in days, frequence of in-patient treatment after discharge, time until closure of a pancreatic fistula (missing excretion of enzyme-rich fluid), quality of life (EORTC-questionaire)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Allgemein-, Viszeral- und Transplantationschirurgie, Heidelberg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2010/12/12**
- Target Sample Size: **150**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

patients equal or older than 18 years planed for elective open distal pancreatectomie Informed consent.

Exclusion criteria

contribution in an other clinical trial, signs for obstruction in the pancreatic head, immunsupressive medication (corticoids more than 40 mg corticoids each day, azathioprin)

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

Klinik für Allgemein-, Visceral- und Transplantationschirurgie
Chirurgische Universitätsklinik Heidelberg

Institutional budget, no external funding (budget of sponsor/PI)

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Germany

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E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

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.*