

## Trial Description

### Title

**Progressive post-resection program after pancreatic resection for malignoma and pre-cancerous lesions of the pancreas**

### Trial Acronym

**pPRP**

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**In 2010 more than 16.000 patients developed pancreatic cancer in germany, and almost as many died of pancreatic cancer.**

**This study is designed to assess whether intensified physiotherapy improves quality of life after pancreatic resection.**

**We will include patients after pancreatic resection due to pancreatic cancer, cancer of the distal biliary tract system, neuroendocrine tumours, periampullary carcinoma, duodenal carcinoma or intraductal papillary mucinous neoplasia (IPMN)- a pre-cancerous lesion of the pancreas.**

**The intervention group cohort A (n= 30 patients) participates in an intensified physiotherapy program after pancreatic resection. The intensified physiotherapy program starts 24 hours after removal of the breathing hose with 3x10min per day physical activity by means of a bed pedal exerciser. At the beginning of the second postoperative week patients get intensified physiotherapy on 5 days per week respectively consisting of 3x 15min walking and toning exercises.**

**After discharge from hospital patients should walk 45min/day and should continue their toning exercises 3x per week.**

**The control group cohort B (n= 30 patients) receive standard physiotherapy during their in-patient stay.**

**Quality of life will be assessed with the SF-8 and the EORTC-QLQ C30 and PAN26 questionnaires.**

**In case of positive results, a (multicentric) study with corresponding power will follow this pilot trial.**

**The progressive post-resection program should be completed by a structured follow-up.**

**In the context of this study all patients receive a CT-scan 6 and 12 months after surgery.**

### Brief Summary in Scientific Language

**In 2010 more than 16.000 patients developed pancreatic cancer in germany, and almost as many died of pancreatic cancer. In 2010 the german relative 5-year survival rate for patients with pancreatic cancer was 8%. The age-standardised morbidity- and mortality rates remain nearly constant, but due to an ageing population there is an increase in the absolute number of cases.**

**At the time of the first diagnosis only 15-20% of patients with pancreatic cancer present with a resectable disease.**

**Until now there are only a few studies developing programs to increase quality of life after pancreatic resection.**

**This study is a prospective randomized controlled intervention study, which is initially designed as a pilot trial.**

**Patients with resectable pancreatic cancer, cancer of the distal biliary tract, neuroendocrine tumours, periampullary carcinoma, duodenal carcinoma or intraductal papillary mucinous neoplasia (IPMN) will be included.**

**After pancreatic resection the intervention group cohort A (n= 30 patients) participates in an intensified physiotherapy program. The control group cohort B (n= 30 patients) gets the standard physiotherapy of the pancreatic cancer center, Pius-Hospital, Oldenburg, Germany. Both groups receive nutritional consulting and if needed the substitution of endocrine/exocrine pancreatic insufficiency.**

**Quality of life will be assessed with the SF-8 and the EORTC QLQ-C30 and PAN26 questionnaires.**

**The aim of the study is to assess whether intensified physiotherapy increases quality of life after pancreatic resection.**

**A (multicenter) study with corresponding power will follow in case of favourable results of this pilot trial.**

**The progressive post-resection program should be completed by a structured follow-up.**

**In line with this study all patients get a CT-scan 6 and 12 months after surgery for follow-up.**

## Organizational Data

- DRKS-ID: **DRKS00006786**
- Date of Registration in DRKS: **2014/10/01**
- 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.: **Drs.59/2014 , Kommission für Forschungsfolgenabschätzung und Ethik Oldenburg**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **C25 - Malignant neoplasm of pancreas**

## Interventions/Observational Groups

- Arm 1: **The intervention group cohort A (n= 30 patients) participates in an intensified physiotherapy program after pancreatic resection. The intensified physiotherapy program starts 24 hours after removal of the breathing hose with 3x10min per day physical activity by means of a bed pedal exerciser. At**



**the beginning of the second postoperative week patients get intensified physiotherapy on 5 days per week respectively consisting of 3x 15min walking and toning exercises.**

**After discharge from hospital patients should walk 45min/day and should continue their toning exercises 3x per week.**

- **Arm 2: The control group cohort B (n= 30 patients) receive standard physiotherapy during their in-patient stay. The standard physiotherapy consists of 20min on 5days/week individual therapy with recreational- and mobilisation exercises, walking and if possible stair climbing**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*
- Allocation: **Randomized controlled trial**
- Blinding: [---]\*
- Who is blinded: [---]\*
- 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

**Quality of life of the intervention group taking part in an intensified physiotherapy program 12 months after pancreatic resection assessed with the SF-8 and the EORTC QLQ-C30 and PAN26 questionnaires in the validated german translation.**

## Secondary Outcome

- **Impact on the 1-year survival rate**
- **Recurrence rate after 6 and 12 months**
- **Breakup rate**
- **Progress in quality of life (preoperative, after 1 week and after 3,6,12 months)**
- **Physical performance assessed by the "short physical performance batterie"(preoperative, after 1week and after 3,6,12 months)**
- **Physical performance assessed by ergometry (preoperative and after 3,6,12 months)**
- **Nutritional status of the patients assessed by specific blood metabolism parameters (preoperative, after 1 week and after 3,6,12 months)**
- **Nutritional status and physical performace assessed by body fat measurement with the 7-folds calipter method (preoperative, after 1 week and after 3,6,12 months)**
- **Effect of accompanying therapie (radio-/chemotherapy) on quality of life and physical performance**
- **Individual consideration of the 2 scores of the SF-8 questionnaire: "physical**



**component score" and "mental component score"**  
**- Individual consideration of the 3 domains of the EORTC QLQ-PAN26 questionnaire: "disease-specific symptoms", "functional status" and "psycho-social well-being"**

## Countries of recruitment

- **DE Germany**

## Locations of Recruitment

- University Medical Center **Viszeralchirurgie, Pius-Hospital, Oldenburg**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/02/01**
- Target Sample Size: **60**
- 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 with resectable pancreatic cancer, cancer of the distal biliary tract, neuroendocrine tumour, periampullary carcinoma, duodenal carcinoma, intraductal papillary mucinous neoplasia (IPMN)**
- **Age  $\geq$  18 years**
- **Surgery and postoperative treatment in the Department of General- and Visceral Surgery, Pius-Hospital, Oldenburg, Germany**

## Exclusion criteria

- **Missing informed consent**
- **Physical inability to take part at the intensified physiotherapy program**
- **Analphabetism**
- **Inability of german language**
- **Physical/Mental disability to take part at the intensified physiotherapy program**
- **Surgery due to chronic (recurrent) pancreatitis or acute pancreatitis**

**- Insufficient compliance**

## Addresses

### ■ Primary Sponsor

**Klinik für Allgemein- und Viszeralchirurgie Pius-Hospital Oldenburg**  
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### ■ Contact for Scientific Queries

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### ■ Contact for Public Queries

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## Sources of Monetary or Material Support

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

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## Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- 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.