Trial Description

Title

Pylorus resection versus pylorus preservation in pancreatoduodenectomy: A multicenter surgical registry-based randomized active-controlled trial (RRCT) from the German DGAV StuDoQ|Pancreas Registry

Trial Acronym

PyloResPres-TRIAL

URL of the trial

[---]*

Brief Summary in Lay Language

As part of a partial pancreatoduodenectomy (PD), two different strategies for the separation of the gastrointestinal passage are applied orally. This is on the one hand the resection (prPD) and on the other the receipt (ppPD) of the pylorus. Delayed gastric emptying (DGE) after PD is a serious complication that can occur following both strategies (ppPD or prPD). Existing metaanalyzes that examine the DGE after performing one of the two methods still produce conflicting results. Large, multicenter randomized controlled trials (RCTs) on this topic do not exist. The proposed study will now address this very shortcoming. In a prospective multi-centric and register-based RCT (RRCT), the effectiveness of ppPD should be compared with that of prPD in German nationwide reality. This novel study design allows a better transferability of the results.

Brief Summary in Scientific Language

As part of a partial pancreatoduodenectomy (PD), two different strategies for the separation of the gastrointestinal passage are applied orally. This is on the one hand the resection (prPD) and on the other the receipt (ppPD) of the pylorus. Delayed gastric emptying (DGE) after PD is a serious complication that can occur following both strategies (ppPD or prPD). Existing metaanalyzes that examine the DGE after performing one of the two methods still produce conflicting results. Large, multicenter randomized controlled trials (RCTs) on this topic do not exist. The proposed study will now address this very shortcoming. In a prospective multi-centric and register-based RCT (RRCT), the effectiveness of ppPD should be compared with that of prPD in German nationwide reality. This novel study design allows a better transferability of the results.

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

No

Description IPD sharing plan

[---]*

[---]*

Organizational Data

- DRKS-ID: **DRKS00018842**
- Date of Registration in DRKS: **2019/10/24**
- 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.: **19-221 , Ethik-Kommission der Medizinischen Fakultät der Ludwig-Maximilians-Universität München**

Secondary IDs

Health condition or Problem studied

- ICD10: **K31.9 - Disease of stomach and duodenum, unspecified**
- ICD10: **T81.9 - Unspecified complication of procedure**

Interventions/Observational Groups

- Arm 1: **pylorus preserving group (ppPP)**
- Arm 2: **pylorus resecting group (prPD)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary efficacy endpoint is the frequency of postoperative DGE (delayed gastric emptying) according to the international ISGPS definition 30 days after index operation, compared between the two intervention groups

Secondary Outcome

severe morbidity (Clavien Dindo classification<3b vs ≥3b), blood loss (ml), 30 day mortality (death from any cause), postoperative hospital stay, insufficiency of the gastro/pylorojejunostomy, operation time, initiation of adjuvant chemotherapy in cancer patients

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **LMU München Klinikum Großhadern, München**
- Medical Center **Klinik für Allgemein-, Viszeral- und Onkologische Chirugie, Klinikum Bremen-Mitte/Bremen-Ost, Bremen**
- Medical Center **Klinik für Allgemein-, Thorax-und Viszeralchirugie, Städtisches Klinikum Dresden Friedrichstadt, Dresden**
- Medical Center **Klinik für Allgemein- und Viszeralchirugie, Helios Klinikum Erfurt, Erfurt**
- University Medical Center **Chirurgische Klinik Universitätsklinikum Erlangen, Erlangen**
- Medical Center **Klinik für Allgemein-, und Viszeralchirurgie Alfred Krupp Krankenhaus Essen, Essen**
- University Medical Center **Klinik für Allgemein- und Viszeralchirurgie, Universitätsklinikum Freiburg, Freiburg im Breisgau**
- Medical Center **Klinik für Allgemein-, und Viszeralchirurgie,chirurgische Onkologie, Asklepios KlinikBarmbeck ,Hamburg, Hamburg**
- Medical Center **Klinik für Allgemein-, Viszeral- und Transplantationschirurgie Westpfalz-KlinikumGmbH Kaiserslautern, Kaiserslautern**
- University Medical Center **Klinik für Chirurge, UniversotätsklinikumSchleswig Holstein Campus Lübeck, Lübeck**
- University Medical Center **Klinik für Viszeral-, Thorax- und Gefäßchirurgie Universitätsklinikum Marburg, Marburg**
- Medical Center **Klinik für Allgemein-, Viszeral-, Thorax- und Gefäßchirurgie Klinikum Memmingen, Memmingen**
- University Medical Center **Klinik und Poliklinik für Chirurgie KlinikumRechts der Isar der TU München, München**
- Medical Center **Klinik für Allgemein- und Viszeralchirurgie Krankenhaus Barmherzige Brüder Regensburg, Regensburg**

- Medical Center **Klinik für Allgemein- und Viszeralchirurgie St.Josephs Krankenhaus Wiesbaden, Wiesbaden**
- University Medical Center **Universitätsklinik für Allgemein-, Viszeral- und Thoraxchirurgie der Paracelsus Medizinischen Privatuniversität, Nürnberg**
- Medical Center **Niels-Stensen-Kliniken Marienhospital Osnabrück, Osnabrück**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/11/26**
- Target Sample Size: **982**
- 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

**Patients in which a partial pancreatoduodenectomy (PD) needs to be performed
Any patient aged 18 years or older scheduled for PD for any indication with written informed consent is eligible**

Exclusion criteria

**-Patients who participate in another intervention trial interfering with the surgical intervention or the outcome of this Trial
-Patients with expected lack of compliance and/or irreconcilable language barriers will be excluded
-Classic Whipple operation**

Addresses

- **Primary Sponsor**

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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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Status

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

Trial Publications, Results and other documents

- trial protocol (mandatory for transfer to Studybox) **Study Protocol**

** 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.*