

Trial Description

Title

Intravenous vs. epidural analgesia to reduce the incidence of gastrointestinal complications after elective pancreatoduodenectomy

Trial Acronym

PAKMAN

URL of the trial

[---]*

Brief Summary in Lay Language

The effective treatment of pain after surgery has a positive effect on the recovery of patients. For major surgical procedures of the pancreas, pain management is already initiated during surgery and continued after surgery for several days as needed to alleviate pain sufficiently.

Currently, there are two different standard applications: one is the intravenous (administered through a vein) patient-controlled pain treatment, abbreviated IV-PCA, the other is the epidural (administered via a catheter near the spinal cord) pain treatment, abbreviated EDA.

The aim of the PAKMAN trial is to compare both procedures with respect to the occurrence of complications of the gastrointestinal tract (e.g. pancreatic fistula).

Brief Summary in Scientific Language

The most common strategies for pain management in pancreatic surgery are either combined intraoperative general and epidural anesthesia and postoperative epidural analgesia (EDA) or intraoperative general anesthesia and postoperative patient-controlled intravenous analgesia (IV-PCA). Unfortunately, patients undergoing pancreatoduodenectomy often suffer from gastrointestinal complications, e. g. pancreatic fistula, delayed gastric emptying, biliary leakage, gastrointestinal bleeding, postoperativ ileus. Based on a previous trial, the aim of the PAKMAN trial is to compare These two procedures regarding the frequency of complications in a multicenter RCT setting. A total of 370 patients need to be randomized.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00007784**
- Date of Registration in DRKS: **2015/03/23**
- 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-073/2015 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Intraoperative general anesthesia and postoperative patient-controlled intravenous analgesia (IV-PCA).**
- Arm 2: **Combined intraoperative general and epidural anesthesia and postoperative epidural analgesia (EDA).**

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

Combined endpoint of gastrointestinal complications (Delayed gastric emptying, pancreatic fistula, biliary leak, gastrointestinal bleeding, postoperative ileus) until postoperative day 30.

Secondary Outcome

- **Delayed gastric emptying**
- **Pancreatic fistula**
- **Biliary leak**
- **Gastrointestinal bleeding**
- **Postoperative ileus**
- **Combined endpoint of infectious complications (pneumonia, urinary tract infection, wound infection intraabdominal abscess, sepsis)**
- **Hospital stay / ICU stay / readmission until postoperative day 30**
- **Mortality**
- **Morbidity until postoperative day 30**
- **Frequency of blood transfusions**
- **Amount of given vasopressors during operation**
- **Pain control with numeric rating scale (NRS)**
- **Amount of given fluids**
- **Weight over time/weight changes**
- **SAE**

Countries of recruitment

- **DE Germany**
- **IT Italy**
- **AT Austria**
- **SI Slovenia**

Locations of Recruitment

- University Medical Center **Klinik für Allgemein-, Viszeral- und Transplantationschirurgie , Heidelberg**
- University Medical Center <style fontName='DejaVu Sans' isBold='true'>Klinik & Poliklinik für Allgemein- und Viszeralchirurgie, Gefäß- und Kinderchirurgie, Würzburg</style>
- Medical Center **Klinik für Allgemein-, Viszeral-, Thorax- und Transplantationschirurgie, Stuttgart**
- University Medical Center **Klinik für Allgemeine Chirurgie , Lübeck**
- University Medical Center **Klinik für Allgemein-, Viszeral-, Thorax-, Transplantations- und Kinderchirurgie, Gießen**
- University Medical Center **Chirurgische Klinik, Department für Allgemein- und Viszeralchirurgie, Freiburg im Breisgau**
- University Medical Center **University Medical Centre Ljubljana, Ljubljana**
- Medical Center **Krankenhaus der Barmherzigen Brüder St. Veit an der Glan, St. Veit an der Glan**

- University Medical Center **University Hospital Trust/Verona University Hospital, Verona**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/06/30**
- Target Sample Size: **370**
- 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

- **Patients scheduled for elective pancreatoduodenectomy**
- **Age \geq 18 years**
- **Ability of subject to understand character and individual consequences of the clinical trial**
- **Written informed consent**

Exclusion criteria

- **Chronic pancreatitis**
- **Severe COPD (Stage III according to GOLD criteria)**
- **American Society of Anesthesiologists (ASA) physical status classification \geq IV**
- **Patients with chronic pain syndrome due to any reason**
- **Presence of contraindication(s) to the use of patient-controlled intravenous analgesia or epidural analgesia**
- **Participation in another intervention-trial with interference of intervention and outcome of this study**
- **Language problems**

Addresses

- **Primary Sponsor**
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Primary Sponsor

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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

**Förderrichtlinien Geförderte Projekte Metropolregion Rhein-Neckar
Dietmar Hopp Stiftung gGmbH**

Private sponsorship (foundations, study societies, etc.)

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URL: **http://dietmar-hopp-stiftung.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2017/09/19**

Trial Publications, Results and other documents

- Paper **Klotz R, Larmann J, Klose C, Bruckner T, Benner L, Doerr-Harim C, Tenckhoff S, Lock JF, Brede EM, Salvia R, Polati E, Köninger J, Schiff JH, Wittel UA, Hötzel A, Keck T, Nau C, Amati AL, Koch C, Eberl T, Zink M, Tomazic A, Novak-Jankovic V, Hofer S, Diener MK, Weigand MA, Büchler MW, Knebel P; PAKMAN Trial Group. Gastrointestinal Complications After Pancreatoduodenectomy With Epidural vs Patient-Controlled Intravenous Analgesia: A Randomized Clinical Trial. JAMA Surg. 2020 May 27:e200794.**

* 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.