ISRCTN59731654 https://doi.org/10.1186/ISRCTN59731654

A novel surgical technique for preventing pancreatic leakage after attaching the pancreas to the small intestine

Submission date
11/11/2019

Recruitment status
Stopped

Registration date
06/12/2019

Overall study status
Stopped

Last Edited
21/06/2024

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Pancreaticoduodenectomy (PD) is a major surgical procedure for the treatment of tumors in the upper small intestine. This procedure is very complicated with many steps and more injury and requires digestive tract reconstruction after resection. Although it has been improved for several decades, postoperative complication rate and mortality rate remain high, and approximately 50% of patients will have complications. Liberated pancreatic juice from leakage corrodes the stump of the gastroduodenal artery (GDA), which causes secondary hemorrhage and even death. How to decrease the incidence of pancreatic fistula after PD is currently an increasing area of research in pancreatic surgery.

In this study, we will develop a novel pancreatojejunal technique based on “Pair-Watch" suturing technique, "wall" technique, and "forced healing" technique. This technique will be expected to integrate the advantages of three techniques to reduce the incidence of pancreatic fistula and mitigate pancreatic fistula-related hemorrhage after PD and lay a favorable foundation for enhanced recovery after surgery.

Who can participate?
Patients with highly suspected periampullary tumors.

What does the study involve?
Patients will be randomised to receive either the new surgical technique or the current standard technique during the surgery.

What are the possible benefits and risks of participating?
This novel pancreaticojejunostomy technique may further reduce the incidences of pancreatic leakage and hemorrhage after pancreaticoduodenectomy and improve the prognosis of patients. The results of this study may be of great significance for the treatment of more patients and the promotion of medical development in the future. The doctor will closely

observe the patient’s condition change and deal with it in time to ensure the patient’s safety. Patients will be informed of any changes and any newly identified adverse reactions during the study process.

Where is the study run from?
Shengjing Hospital of China Medical University, China

When is the study starting and how long is it expected to run for?
December 2019 to June 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Xiaodong Tan
tanxd@sj-hospital.org

Contact information

Type(s)
Public

Contact name
Prof Xiaodong Tan

ORCID ID
https://orcid.org/0000-0003-0862-1306

Contact details
No. 36 Sanhao Street
Heping District
Shenyang
China
110004
+86 (0)249661531111
tanxd@sj-hospital.org

Additional identifiers

Protocol serial number
1.0

Study information

Scientific Title
Efficacy of a novel pancreaticojejunostomy technique in preventing pancreatic leakage and hemorrhage after pancreaticoduodenectomy: protocol for a randomised controlled trial

Study objectives

We compare the incidence of pancreatic fistula and hemorrhage between the novel pancreaticojejunostomy technique and conventional end-to-side pancreatic duct-to-mucosa anastomosis after pancreaticoduodenectomy (PD), providing data support for application of the novel pancreaticojejunostomy technique in the clinic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/03/2019, Ethics Committee, Shenjing Hospital of China Medical University (No. 36, Sanhao Street, Heping District, Shenyang, Liaoning Province, China; llwyh@sj-hospital.org; +86-024-96615-10027), ref: 2016PS43J

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Periampullary tumors

Interventions
Based on the included eligible patients with highly suspected periampullary tumors, the hospital statisticians will generate a random digital sequence using SAS 9.1 program (SAS Institute Inc., Cary, NC, USA). A random number from the uniform distribution on the interval (0, 1) will be generated for each patient using ranuni function (1 for study group and 0 for control group). These random numbers will be sequenced using proc sort and then divided into two parallel groups at a 1:1 ratio. Eligible patients will be randomized to the study group or the control group according to the assigned digital sequence.

After general anesthesia, an abdominal incision will be made. The greater omentum will be removed. Then gastric antrum will be cut off at 2 cm above the pylorus. The pylorus and duodenum will be completely removed (including pancreatic head, gallbladder, and common bile duct pancreas with tumors as well as 15 cm long proximal jejunum). The digestive tract will be reconstructed by child pancreaticojejunostomy
.
Study group: The pancreatic duct and the jejunum will be anastomosed using a “Pair-Watch” suturing technique in combination with transverse mesocolon blocking method (“forced healing” technique). In addition, the transverse mesocolon will be used as the “wall” to prevent contact of the liberated pancreatic juice with the GDA stump. Pancreatojejunal anastomosis will be performed using a valgus anastomosis method through suturing and knot tying.

Control group: The annular end of the pancreas will be placed in the jejunal wall. The posterior capsule of the pancreas will be first interruptedly sutured with the muscular layer of the jejunal serosa. Then the middle part including the pancreatic duct and its surrounding pancreatic tissue will be interruptedly sutured with the opening of the jejunum. Finally, the anterior capsule of the

pancreas will be intermittently sutured with the muscular layer of the jejunal serosa. The proximal jejunum will be sutured with the hepatic duct through an end-to-side anastomosis. End-to-side duodenal to jejunal anastomosis will be accomplished.

All patients will be followed up for 30 days.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Incidence of pancreatic fistula within 30 days after surgery (defined as an abdominal drain or incision output of fluid with an amylase level > 3 times the upper limit of institutional normal serum amylase activity for 3 days)

Key secondary outcome(s)
1. Incidence of postoperative hemorrhage within 30 days of surgery (defined as bloody drainage fluid, hematemesis, melena, unexplained hypotension or tachycardia, abnormal laboratory tests, and aggravated clinical manifestations) evaluated based on the results of gastrointestinal endoscopy, angiography, perfusion imaging, CT or re-operation
2. Incidence of delayed gastric emptying:
2.1. Grade A delayed gastric emptying: indwelling nasogastric tubes for 4-7 days after surgery or re-indwell nasogastric tubes 3 days after surgery because of nausea and vomiting or being unable to tolerate solid food 7-14 days after surgery
2.2. Grade B delayed gastric emptying: indwelling nasogastric tubes for 8-14 days after surgery or re-indwell nasogastric tubes 7 days after surgery, or being unable to tolerate solid food 14-21 days after surgery
2.3. Grade C delayed gastric emptying: indwelling nasogastric tubes for over 14 days or re-indwell nasogastric tubes 14 days after surgery or being unable to tolerate solid food 21 days after surgery
3. Surgical indicators: Patient’s operation time and intraoperative blood loss
4. Economic indicators: Patients’ average hospital stay and hospitalization cost

Completion date
30/06/2024

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Periampullary tumors indicated by at least two imaging examinations or pathological biopsy before surgery
2. ≥18 years of age
3. Provision of written informed consent by patients or their legal guardians

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Extensive tumor metastasis
2. Abnormal blood coagulation
3. Renal dysfunction (creatinine >250 μmol/L)
4. Chronic liver disease
5. History of radiation therapy
6. American Society of Anesthesiologists (ASA) class IV-V
7. Life expectancy <48 hours
8. Lactating or pregnant women
9. Participation in other drug clinical trials

Date of first enrolment
01/12/2019

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
China

Study participating centre
Shengjing Hospital of China Medical University
No. 36 Sanhao Street
Heping District
Shenyang
China
110004

Sponsor information

Organisation
Shenjing Hospital of China Medical University

ROR
https://ror.org/0202bj006

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other