Closure of the pancreatic duct after distal pancreatectomy

Published: 21-01-2010
Last updated: 04-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON32526

Source
ToetsingOnline

Brief title
CRP (Closure pancreatic remnant)

Condition

- Gastrointestinal therapeutic procedures

Synonym
Pancreatic lesons of the body and tail

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Pancreas research fonds

Intervention

Keyword: distal pancreatectomy, pancreatic remnant

Outcome measures

Primary outcome

The primary outcome is the development of pancreatic fistula. A pancreatic fistula develops when the closure of the pancreatic remnant fails to heal, causing a leak of pancreas- derived, enzyme-rich fluid from the pancreatic ductal system.

A pancreatic fistula is defined as drainage of greater than 50 mL amylase-rich fluid (> 3-fold elevation above upper limit of normal in serum) per day through the drains

on or after postoperative day 10.

Pancreatic fistulas will be graded according to international fistula definition as published by Strasberg based on the clinical impact on the patient*s hospital course.

Grade 1 Deviation from normal postoperative course without pharmacologic, endoscopic, surgical or radiologic intervention (certain drugs allowed)

Grade 2 Pharmacologic treatment needed. Includes blood transfusions and total parenteral nutrition

Grade 3 (a/b) Surgical, endoscopic or interventional radiologic treatment needed

a: Not under general anaesthesia b: Under general anaesthesia

Grade 4 (a/b) Life threatening complications and organ dysfunction

a: Single organ b: Multi-organ

Grade 5 Death due to pancreatic fistula

Secondary outcome

Secondary endpoints are mortality, morbidity and costs.

The mortality rate is defined as the total in-hospital death rate.

Postoperative complications, especially delayed gastric emptying, which is defined as a nasogastric tube for more than 10 days after surgery, inability to proceed to a regular diet within 10 days or vomiting for more than 3 consecutive days after the fifth post-operative day.

Length of hospital stay

Medical costs

Study description

Background summary

Appropriate closure of the pancreatic remnant after distal pancreatectomy is still debated. A variety of procedures have been recommended to reduce the frequency of pancreatic fistula. Resections of the pancreas reaching the left side of the superior mesenteric vein are defined as distal pancreatectomy. They are performed less often than resections of the pancreatic head (20 to 30% of all pancreatic resections owing to a lower incidence of pancreatic disease and later appearance of clinical symptoms in this part of the organ. However, continuously improving imaging and diagnostic techniques have resulted in an increase in the frequency of the procedure. Most resections are performed electively (84 per cent) for the following indications: chronic pancreatitis (24 per cent), other benign diseases (22 per cent), malignant diseases (18 per cent), neuroendocrine tumours (14 per cent) and cysts of the pancreas (6 per cent). The remaining 16 per cent are emergencies after abdominal trauma.In recent years the mortality rate after pancreatic resection has decreased

considerably to between 0 and 6 per cent in high-volume centres, but morbidity remains high, ranging from 10 to 47 per cent Pancreatic fistula and leakage are the most common and clinically relevant complications, and they are thought to depend on surgical technique and skill. Because fistula is associated with local and general complications (pancreatic fluid collection, formation of intra-abdominal abscesses, wound infection, delayed gastric emptying, respiratory complications, sepsis), it has important implications for the patient, the surgeon and the healthcare system. In general, it prolongs hospital stay for specialized treatment, including re-operation and drainage.
The appropriate technique for closure of the pancreatic remnant is still debated. There is no evidence whether stapled or hand sewn closure should be preferred. Since stapled closure is not recommended for the triangular pancreas, the thick pancreas (> 1.5 cm), the firm or non-compressible pancreas and in case of a resection plane to the right of the gastroduodenal artery, in this study we will use a standardized hand sewn closure.
Topical hemostatic agents applied to the resection surface of the remnant liver after partial liver resection have shown to be effective in preventing postoperative bleeding. The group of van Gulik showed that application of topical hemostatic agents, such as fibrinogen/thrombincoated collagen patch (TachoSil®, Nycomed, UK Ltd.) has a biliostatic effect, which can be considered an additional benefit of the use of these devices. The adhesive strength of TachoSil on the resection surface, however, was superior to other agents.
Results of retrospective studies on recostruction techniques after pancreatico-duodenectomy suggest that outcome with regard to pancreatic fistula can be improved using TachoSil®.

Study objective

The proposed study is a multicentre randomised controlled trial investigating the effect of Tachosil sealing of the pancreatic remnant after distal pancreatoduodenectomy on the development of pancreatic fistula.
Patients will be randomised to either Tachosil sealing of the pancreatic remnant after standardized hand sewn closure or conventional closure alone.
Primary endpoint will be the development of pancreatic fistula.
Secondary endpoints will be overall mortality and morbidity and a cost effectiveness analysis.

Study design

Prospective randomized controlled multi-centre trial with blinding for treatment allocation of patients and medical personnel except for the surgeon.
Patients will be evaluated according to the inclusion criteria at the outpatient clinic of participating centres. If eligible, informed consent is obtained. Inclusion will start after approval of Medical Research Ethical Committee

Intervention

Conventional closure of the pancreatic remnant
After complete mobilisation of the pancreatic body or tail (up to the region of the superior mesenteric vein, or at least 2-3 cm central of the planned resection margin), the resection is performed with a surgical scalpel or diathermia. After haemostasis the pancreatic duct is closed separately using PDS 4x0 or 5x0. The pancreatic remnant is closed using continuous mattress sutures with PDS 3x0 or 4x0.

Closure of the pancreatic remnant by Tachosil seal
In the Tachosil arm, pancreatic resection and transsection of the pancreatic body will be executed with a surgical scalpel. The main pancreatic duct is identified and closed using single stitches of 4-0 or 5-0 PDS. The parenchyma is then closed with single stitches 3x0 or 4x0 PDS. The suture line is reinforced by placement of a fibrin/ thrombin-coated collagen patch (TachoSil) onto the transsected end .All participating centre receive a DVD where this procedure is demonstrated

Study burden and risks

n.a.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients undergoing a distal pancreatectomy

Exclusion criteria

Current immunosuppressive or chemotherapy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2011
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	21-01-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL29396.078.09