

Relaparotomy for pancreatic fistula after pancreatoduodenectomy

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24103

Source

NTR

Brief title

TBA

Health condition

Postoperative pancreatic fistula

Sponsors and support

Primary sponsor: LUMC

Source(s) of monetary or material Support: This work is supported by the Bas Mulder Award [UL2015-7665] from the Alpe d'HuZes foundation/Dutch Cancer Society (J.V. Groen, J.S.D. Mieog). Alexander Suerman stipend (Board of directors, University Medical Centre Utrecht), (F.J. Smits).

Intervention

Outcome measures

Primary outcome

Mortality

Secondary outcome

New-onset organ failure, pancreatectomy specific complication in accordance to the International Study Group on Pancreatic Surgery definitions and grading (i.e. postpancreatectomy hemorrhage, bile leakage, delayed gastric emptying, chyle leak), length of Intensive Care Unit (ICU) stay, length of hospital stay, duration of pancreatic fistula (calculated as time from pancreatoduodenectomy to completion pancreatectomy or removal of last abdominal drain), the number and type of subsequent invasive interventions after first relaparotomy for pancreatic fistula, adjuvant therapy, development of postoperative new endocrine and exocrine pancreatic insufficiency

Study description

Background summary

Postoperative pancreatic fistula is the most notorious complication after pancreatoduodenectomy for it is associated with a high mortality. In the management of severe pancreatic fistula, a minimally invasive approach appears to be superior to relaparotomy in terms of mortality. However, a minimally invasive management strategy is not successful in all patients. A small number of patients with fulminant pancreatic fistula might ultimately require surgical intervention. During relaparotomy, different strategies have been identified: surgical drainage, completion pancreatectomy, disconnection of pancreatic anastomosis with preservation of the remnant, salvage pancreaticogastrostomy, redo of the pancreatic anastomosis and repair of the pancreatic anastomosis. Completion pancreatectomy is the most aggressive treatment in which the focus of the inflammation is removed completely, a downside of this procedure is the subsequent brittle diabetes. On the other side, pancreas preserving procedures might not be sufficient and thereby lead to further deterioration and prolong hospital stay. In the current literature there is only little written on the clinical outcomes of different surgical treatment strategies, including timing of completion pancreatectomy, in patients with fulminant postoperative pancreatic fistula. The aim of this study is to evaluate surgical treatment strategies, including timing of completion pancreatectomy and the clinical outcome in patients with severe pancreatic fistula after pancreatoduodenectomy requiring a relaparotomy.

Study objective

We hypothesize that a minimally invasive approach during the first relaparotomy for pancreatic fistula is associated less mortality. Due to the retrospective design results should be interpreted with caution. Possibly there still are specific patient who would benefit from a more invasive approach (i.e. completion pancreatectomy).

Study design

Total duration: From December 2018 – December 2019.
Data collection and analysis: From December 2018 – July 2019.
Writing and publishing manuscript: From July 2019 – December 2019.

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

Patients undergoing relaparotomy for pancreatic fistula after pancreatoduodenectomy

Exclusion criteria

-

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control: N/A , unknown

Recruitment

NL

Recruitment status: Other

Start date (anticipated): 11-03-2019

Enrollment: 140

Type: Unknown

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date: 11-03-2019

Application type: First submission

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
NTR-new	NL7596
Other	METC LUMC : G17.059

Study results