

Relaparotomy for pancreatic fistula after pancreatoduodenectomy

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Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24103

Bron

NTR

Verkorte titel

TBA

Aandoening

Postoperative pancreatic fistula

Ondersteuning

Primaire sponsor: LUMC

Overige ondersteuning: 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).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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. complection pancreatectomy).

Onderzoeksopzet

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.

Contactpersonen

Publiek

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Wetenschappelijk

LUMC
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients undergoing relaparotomy for pancreatic fistula after pancreatoduodenectomy

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Anders
(Verwachte) startdatum: 11-03-2019
Aantal proefpersonen: 140
Type: Onbekend

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 11-03-2019
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7596
Ander register	METC LUMC : G17.059

Resultaten