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<b>Ethical review</b>	Approved
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### Brief title

FIBROPANC

### Health condition

Malignant and premalignant periampullary tumors, excluding pancreatic adenocarcinoma.

### Sponsors and support

Primary sponsor :	NA
Source(s) of monetary or material Support :	Grant application follows

### Intervention

### Outcome measures

#### Primary outcome

Safety (maximum of 3 patients with CTCAE grade 3-4-5 complications) and efficacy (significant change in the within-patient durometer measurements of radiated and non-radiated pancreatic texture) of preoperative radiotherapy.

## Secondary outcome

POPF Grade B and C

## Study description

### Background summary

Rationale: Postoperative pancreatic fistula (POPF) is a potential life-threatening complication after pancreatoduodenectomy. POPF is caused by an anastomotic dehiscence of the pancreato-jejunostomy or pancreato-gastrostomy created in the reconstruction phase of a pancreatoduodenectomy (i.e. Whipple) procedure. It occurs in approximately 15% of all patients undergoing pancreatoduodenectomy and is the primary cause of complications after this procedure, associated with increase in length of hospital stay, radiological or surgical interventions, higher readmission rates, higher costs and even death in up to 25-30% of patients with POPF. Soft pancreatic texture, small pancreatic duct diameter, high BMI and male sex are well-known risk factors for the development of POPF. Furthermore, patients undergoing pancreatoduodenectomy for diagnoses other than pancreatic ductal adenocarcinoma have a higher risk of POPF. These diagnoses include: distal cholangiocarcinoma, duodenal carcinoma, ampullary carcinoma, pancreatic neuroendocrine tumor, intraductal papillary mucinous neoplasm (IPMN), or symptomatic benign lesions in the periampullary region. In patients with a tumor of the peri-ampullary region and a narrow pancreatic duct diameter, the risk of developing a pancreatic fistula is even over 25%. The recent Dutch multicenter PREOPANC trial found significantly less POPF after pancreatoduodenectomy in patients with pancreatic cancer who had undergone neoadjuvant chemoradiotherapy as compared to patients with upfront surgery. This finding is supported by other studies. The hypothesis is that radiotherapy leads to fibrosis which is hardening the pancreatic tissue, hereby decreasing the risk of POPF.

In the current study, we hypothesize that a single course of 12Gy preoperative radiotherapy may lead to sufficient fibrosis in a small (4cm) targeted area of pancreatic tissue where the anastomosis with either the jejunum will be created, thereby reducing the risk of grade B and C POPF in patients at high risk of developing this complication after pancreatoduodenectomy. Objective: To investigate the feasibility and safety of preoperative stereotactic radiotherapy of 4cm pancreas in patients undergoing pancreatoduodenectomy at high risk (>25%) of developing POPF.

### Study objective

The hypothesis is that a single course of 12Gy preoperative radiotherapy may lead to sufficient fibrosis in a small (4cm) targeted area of pancreatic tissue where the anastomosis

with either the jejunum will be created, thereby reducing the risk of grade B and C POPF in patients at high risk of developing this complication after pancreatoduodenectomy.

## Study design

Anually

## Intervention

Preoperative radiotherapy delivered in a single fraction of 12 Gy focussed on 4cm pancreas at the intended (i.e. future) anastomotic site.

## Contacts

### Public

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### Scientific

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## Eligibility criteria

### Inclusion criteria

- Patients scheduled to undergo pancreatoduodenectomy for another indication than pancreatic ductal adenocarcinoma.
- Pancreatic duct diameter  $\leq$  3 millimetres, measured on the diagnostic CT scan (at the level of the portomesenteric vein, at the pancreatic neck, the future anastomotic site).
- WHO-ECOG performance status 0,1 or 2.
- Ability to undergo stereotactic radiotherapy and surgery.
- Age  $\geq$  18 years.
- Good understanding of the oral and written patient information provided.

- Written informed consent.

## Exclusion criteria

- Patients undergoing pancreatoduodenectomy for (suspected) pancreatic cancer, chronic pancreatitis, or benign neoplasms (e.g. serous cyst) in the periampullary region.
- Patients with a history of pancreatitis
- Contra-indications for MRI

## Study design

### Design

Study type :	Interventional
Intervention model :	Other
Allocation :	N/A: single arm study
Masking :	Open (masking not used)
No intervention arm :	N/A , unknown

### Recruitment

NL	
Recruitment status :	Recruiting
Start date (anticipated) :	11-02-2021
Enrollment :	33
Type :	Anticipated

### IPD sharing statement

Plan to share IPD :	No
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## Ethics review

Approved	
Date :	23-02-2021
Application type :	First submission

## Study registrations

### (Historical) registrations known in this register

No registrations found

### In other registers

Source :

NTR

<b>Register</b>	<b>ID</b>
NTR-new	NL9299
CCMO	NL72913.018.20

## Study results