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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...

|                             |                       |
|-----------------------------|-----------------------|
| <b>Ethische beoordeling</b> | Goedgekeurd           |
| <b>Status</b>               | Werving gestart       |
| <b>Type aandoening</b>      | -                     |
| <b>Onderzoekstype</b>       | Interventie onderzoek |

## Samenvatting

### Verkorte titel

FIBROPANC

### Health condition

Malignant and premalignant periampullary tumors, excluding pancreatic adenocarcinoma.

### Ondersteuning

Primaire sponsor : NA

Overige ondersteuning : Grant application follows

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

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.

# Toelichting onderzoek

## Achtergrond van het onderzoek

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.

## Doel van het onderzoek

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.

## Onderzoeksoopzet

Annually

## Onderzoeksproduct en/of interventie

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

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

## **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

- 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

## **Onderzoeksopzet**

### **Opzet**

|                   |                         |
|-------------------|-------------------------|
| Type :            | Interventie onderzoek   |
| Onderzoeksmodel : | Anders                  |
| Toewijzing :      | Geen controle groep     |
| Blinding :        | Open / niet geblindeerd |
| Controle :        | N.v.t. / onbekend       |

### **Deelname**

|                          |                 |
|--------------------------|-----------------|
| Nederland                |                 |
| Status :                 | Werving gestart |
| (Verwachte) startdatum : | 11-02-2021      |
| Aantal proefpersonen :   | 33              |
| Type :                   | Gerealiseerd    |

## **Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)**

Wordt de data na het onderzoek Nee gedeeld :

## **Ethische beoordeling**

Goedgekeurd  
Datum : 23-02-2021

Soort :

Eerste indiening

## Registraties

### In dit register bekende (historische) registraties

Geen registraties gevonden

### In overige registers

Source :

NTR

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

## Resultaten