Botulinum toxin (BOTOX®) to prevent post-operative pancreatic fistula in patients who undergo distal pancreatectomy. (PROFIT study)

Gepubliceerd: 16-09-2019 Laatst bijgewerkt: 19-03-2025

Pre-operative peri-ampullary injection of BOTOX® might reduce the incidence of POPF by decreasing intra-ductal pressure via relaxation of the sphincter of Oddi.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22900

Bron
NTR

Verkorte titel
PROFIT

Aandoening

Pancreatic cancer

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Erasmus MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To examine the feasibility and safety of preoperative endoscopic BOTOX® injection in the sphincter of Oddi.

Toelichting onderzoek

Achtergrond van het onderzoek

Despite advances in surgical techniques, the occurrence of postoperative pancreatic fistula (POPF) is still a major cause of potentially severe and costly morbidity after distal pancreatectomy. Good quality evidence on how to prevent POPF is lacking. Existing interventions such as somatostatin analogues, varying surgical closure techniques, pre-operative duct stenting or percutaneous drains, do not work well or have too many complications/side effects. Pre-operative peri-ampullary injection of BOTOX® might reduce the incidence of POPF by decreasing intra-ductal pressure via relaxation of the sphincter of Oddi. In this study we will first analyze the safety and feasibility of peri-ampullar endoscopic BOTOX® injections in a small group of patients (n=15). If the procedure is safe and feasible we will continue this study in an additional 35 patients to investigate whether this procedure indeed reduces the POPF rate.

Doel van het onderzoek

Pre-operative peri-ampullary injection of BOTOX® might reduce the incidence of POPF by decreasing intra-ductal pressure via relaxation of the sphincter of Oddi.

Onderzoeksopzet

Screening
Endoscopic BOTOX injection
Pancreatic surgery
2 weeks post surgery
4 weeks post surgery

Onderzoeksproduct en/of interventie

Pre-operative endoscopic BOTOX® injection. The single BOTOX® injection will consist of a 1 mL suspension of 100 units of BOTOX® reconstituted in 1 mL of 0.9% saline solution will be injected into the sphincter of Oddi (in the one o’clock position).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Age ≥ 18 years.
• Lesion(s) of the body and/or tail of the pancreas for which open, laparoscopic or robot-assisted distal pancreatectomy will be performed.
• Signed informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Hypersensitivity to BOTOX® (or the components in the BOTOX® formulation).
• American Society of Anesthesiologists score >III.
• Unable to undergo duodenoscopy (due to any anatomic condition).
• Pregnancy or lactation.
• Serious concomitant systemic disorders that would compromise the safety of the patient or his/her ability to complete the study, at the discretion of the investigator.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2019
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	16-09-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48251
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8027
CCMO	NL68231.078.19
OMON	NL-OMON48251

Resultaten