

Closure of the Pancreatic Remnant after Distal Pncreatectomy A prospective randomized controlled trial

Gepubliceerd: 08-09-2016 Laatste bijgewerkt: 18-08-2022

Determine which technique for sealing of the pancreatic remnant after distal pancreatectomy optimally closes the pancreatic remnant, leading to the lowest incidence of pancreatic fistula.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24836

Bron

NTR

Verkorte titel

CPR

Aandoening

chronic pancreatitis, cystic pancreatic lesions, malignant pancreatic lesions and neuroendocrine tumors located in the body or tail of the pancreas.

Ondersteuning

Primaire sponsor: Erasmus Medical Center

Overige ondersteuning: Pancreas research fonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

Inappropriate closure of the pancreatic remnant after distal pancreatectomy remains a common source

of morbidity. Pancreatic fistula and leakage are the most common and clinically relevant complications,

and they are thought to depend on surgical technique and skill. A variety of procedures have been

recommended to reduce the frequency of pancreatic fistula. Results of previously described techniques

after pancreatico-duodenectomy suggest that outcome with regard to pancreatic fistula can be

improved using a fibrinogen/thrombin coated collagen patch (TachoSil) in carrying out pancreatico-

jejunostomy. The CPR trial will compare a standard method of hand- or stapled closure of the pancreatic

remnant with or without the use of a collagen patch. If the collagen patch is effective in reducing

pancreatic fistula and overall morbidity it has potential to improve quality of life and reduce medical

costs.

Doel van het onderzoek

Determine which technique for sealing of the pancreatic remnant after distal pancreatectomy optimally closes the pancreatic remnant, leading to the lowest incidence of pancreatic fistula.

Onderzoeksopzet

screening

day of surgery

day 10 post-operative

day 30 post-operative

6 months post-operative

12 months post-operative

Onderzoeksproduct en/of interventie

placement of a collagen patch on the sutured or stapled pancreatic remnant, with a sutured/stapled closed pancreatic remnant as control.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age above 18 years
- Expected survival time more than 12 months

- WHO Karnofsky performance status >50% / ASA I-II
- Patients with chronic pancreatitis, cystic pancreatic lesions, malignant pancreatic lesions and neuroendocrine tumors located in the body or tail of the pancreas.
- patients who are planned to undergo distal pancreatectomy as part of an extensive resection for other malignancies (i.e. sarcoma, GIST, gastric carcinoma).
- written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Current immunosuppressive therapy
- Chemotherapy within 2 weeks before operation
- Curative resection not feasible
- Severe psychiatric or neurologic disease
- Drug and/or alcohol abuse

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2010
Aantal proefpersonen:	250

Type:

Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:

08-09-2016

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	NL5876
NTR-old	NTR6048
Ander register	NL29396.078.09 : MEC-2009-347

Resultaten