

VENous ReSection during pancreatoduodenectomy

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

Samenvatting

ID

NL-OMON26746

Bron

Nationaal Trial Register

Verkorte titel

MULTI-VERS PROJECT

Aandoening

pancreatic cancer; pancreatoduodenectomy; portal vein; vascular resection

Ondersteuning

Primaire sponsor: Leiden University Medical Center

Overige ondersteuning: This work will be supported by the Bas Mulder Award from the Alpe d'HuZes foundation/Dutch Cancer Society [UL2015-7665].

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Morbidity, mortality, overall survival

Toelichting onderzoek

Achtergrond van het onderzoek

Radical tumor resection followed by adjuvant chemotherapy is the current standard treatment of patients with resectable pancreatic cancer.¹ The pre- and intra-operative assessment of portal vein (PV) or superior mesenteric vein (SMV) involvement is particularly important since this resection margin is among the most affected.² PV-SMV resection is indicated if required to aim for a radical resection, as stated by the International Study Group of Pancreatic Surgery.³ A recent meta-analysis showed increased postoperative mortality and worse survival after PV-SMV resection.⁴ The included studies were considered as low evidence and were quite heterogeneous (e.g. low- and high-volume hospitals, time-period: 2006-2014). The short- and long-term outcomes of PV-SMV resection in the Netherlands have not been reported, which will become more important in the near future due to the increasing use of neoadjuvant therapy in borderline and locally advanced pancreatic cancer. The evaluation of tumor extension and PV-SMV involvement on preoperative imaging is also becoming a clinical challenge since the growing use of neoadjuvant therapy.⁵⁻⁷ Moreover, an absence of tumor invasion/approximation is reported in around half of the PV-SMV resections, indicating the difficulties of pre- and intra-operative assessment of PV-SMV involvement.⁸⁻¹⁰ Recent efforts are focussing on utilizing intra-operative imaging modalities for improved tumor extension evaluation (e.g. intra-operative ultrasound, upcoming UltraPanc study; tumor-specific near-infrared fluorescence). The focus of this project is to investigate the current state of art of PVSMV involvement assessment and subsequent resection in relation to the pathological and surgical outcomes in the Netherlands. This platform provides an opportunity for a multidisciplinary approach to PV-SMV resections during pancreatoduodenectomy, hereby ultimately improving the clinical outcomes of patients with pancreatic cancer. Our aim is to investigate 1) discrepancies between pre- and intra-operative suspected PV-SMV involvement and histopathology findings in patients undergoing pancreatoduodenectomy with(out) PV-SMV resection for pancreatic adenocarcinoma and 2) short- and long-term outcomes after PV-SMV resection

Onderzoeksopzet

not applicable

Onderzoeksproduct en/of interventie

Venous resection

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Registeren in Dutch Pancreatic Cancer Audit, pancreatoduodenectomy, 2013-2017,
pancreatic adenocarcinoma

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

not applicable

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-10-2018
Aantal proefpersonen:	1200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	22-11-2018
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	NL6775
NTR-old	NTR7644
Ander register	Commissie Medische Ethiek LUMC : G18.103

Resultaten