

# VENous ReSection during pancreatoduodenectomy

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON26746

### Source

Nationaal Trial Register

### Brief title

MULTI-VERS PROJECT

### Health condition

pancreatic cancer; pancreatoduodenectomy; portal vein; vascular resection

## Sponsors and support

**Primary sponsor:** Leiden University Medical Center

**Source(s) of monetary or material Support:** This work will be supported by the Bas Mulder Award from the Alpe d'HuZes foundation/Dutch Cancer Society [UL2015-7665].

## Intervention

## Outcome measures

### Primary outcome

Morbidity, mortality, overall survival

### Secondary outcome

## Study description

### Background summary

Radical tumor resection followed by adjuvant chemotherapy is the current standard treatment of patients with resectable pancreatic cancer.<sup>1</sup> 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.<sup>2</sup> PV-SMV resection is indicated if required to aim for a radical resection, as stated by the International Study Group of Pancreatic Surgery.<sup>3</sup> A recent meta-analysis showed increased postoperative mortality and worse survival after PV-SMV resection.<sup>4</sup> 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.<sup>5-7</sup> 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.<sup>8-10</sup> 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

### **Study design**

not applicable

### **Intervention**

Venous resection

## **Contacts**

### **Public**

J.V. Groen  
Leiden  
The Netherlands

### **Scientific**

J.V. Groen  
Leiden  
The Netherlands

## **Eligibility criteria**

### **Inclusion criteria**

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

### **Exclusion criteria**

not applicable

## **Study design**

## Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-10-2018
Enrollment:	1200
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	22-11-2018
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
NTR-new	NL6775

**Register**

NTR-old

Other

**ID**

NTR7644

Commissie Medische Ethiek LUMC : G18.103

## Study results