

# Distal pancreatectomy, minimally invasive or open, for malignancy (DIPLOMA)

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To compare MIDP with ODP regarding radical resection rate) for pancreatic ductal adenocarcinoma (PDAC) in the pancreatic body or tail.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON46715

### Source

ToetsingOnline

### Brief title

DIPLOMA-trial

### Condition

- Other condition
- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal therapeutic procedures

### Synonym

Pancreatic adenocarcinoma

### Health condition

Ductaal adenocarcinoom van het pancreas

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Distal pancreatectomy, Minimally invasive surgery, Pancreatic ductal adenocarcinoma

## Outcome measures

### Primary outcome

The primary outcome is microscopically radical resection margins (R0) (these can be in the transection margin of the pancreas but also in the anterior, superior, posterior, inferior margins, i.e. circumferential margins).

### Secondary outcome

Secondary endpoints are:

- Intraoperative parameters (operative time, blood loss, blood transfusion and conversion)
- Postoperative parameters (complications, mortality, re-interventions)
- Pathology parameters (tumor size, lymph node retrieval, positive nodes, invasion, grading and staging)
- Hospitalization parameters (time to functional recovery, tot hospital sta, readmission, intensive care admission)
- Oncology parameters (use of (neo-)adjuvant chemotherapy)
- Quality of life
- Costs

## Study description

### Background summary

Several systematic reviews have suggested superior short term outcomes after minimally invasive distal pancreatectomy (MIDP) as compared to open distal pancreatectomy (ODP) for benign and pre-malignant disease. In the literature and in a recent pan-European survey, about one third of pancreatic surgeons expressed concerns specifically regarding the oncologic safety (i.e. radical resection, lymph node retrieval and survival) of MIDP in pancreatic cancer. Most surgeons stated that a randomised trial assessing oncologic safety in MIDP vs ODP for pancreatic cancer is needed.

### Study objective

To compare MIDP with ODP regarding radical resection rate) for pancreatic ductal adenocarcinoma (PDAC) in the pancreatic body or tail.

### Study design

A pan-European, randomised controlled, multicentre, patient-blinded non-inferiority trial. This protocol was designed according to the SPIRIT guidelines<sup>1</sup>.

### Intervention

Minimally invasive (laparoscopic or robot) distal pancreatectomy

### Study burden and risks

Recent meta-analyses of cohort studies suggest that MIDP is superior to ODP concerning blood loss, complications and hospital stay but data are lacking on oncologic outcomes after MIDP. Subjects will not undergo additional investigations and interventions due to participation in the DIPLOMA trial and therefore risks to subjects involved in this trial are similar to every other patient undergoing distal pancreatectomy in routine clinical practice.

Potential benefits for subjects in the investigational treatment arm could be less intraoperative blood loss, fewer major complications, expedited functional recovery, a shorter hospital stay and better cosmesis.

## Contacts

### Public

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)  
Elderly (65 years and older)

### Inclusion criteria

Age equal or above 18 years;  
Indication for elective distal pancreatectomy for expected PDAC;  
Upfront (without induction / down-sizing radio- or chemotherapy) resectable PDAC in the pancreatic body or tail;  
The tumour can be radically resected via both minimally invasive or open surgery according to the local treating team;  
The patient is fit to undergo distal pancreatectomy, either minimally invasive or open

### Exclusion criteria

ASA-score >3  
History of chronic pancreatitis  
Surgery for secondary tumour  
Distant metastases (M1)  
Tumour involvement of major vessels

Pregnancy  
Participation in study with interference of study outcomes

## Study design

### Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	03-05-2018
Enrollment:	80
Type:	Actual

## Ethics review

Approved WMO	
Date:	25-01-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	30-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

## 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
CCMO	NL63299.018.17