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.

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	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

Secundary 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 guidelines1.

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

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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:	Completed
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