

Pancreatic intra-operative NOdal status: should it influence DEcision making during pancreatoduodenectomy in patients with pancreatic or periampullary cancer?

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28118

Source

NTR

Brief title

PANODE

Health condition

Pancreatic or periampullary malignancy

Sponsors and support

Primary sponsor: Amsterdam UMC

Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

Investigate the effect of lymph node metastases in stations 8a, 9 and 16b1 on overall survival in patients undergoing (classical Whipple or pylorus preserving) pancreatoduodenectomy for pancreatic or peri-ampullary cancer.

Secondary outcome

To determine:

1. The prevalence of lymph node metastases in stations 8a, 9 and 16b1 in histopathologically proven pancreatic or peri-ampullary cancer.
2. In-hospital mortality / conditional survival

Study description

Background summary

Pancreatic cancer carries a poor prognosis. Even after surgical resection median survival is only 16-20 months. Improved patient selection may prevent unnecessary major surgery. Several series have advocated routine sampling of lymph nodes during exploration for pancreatoduodenectomy. It is currently uncertain whether lymph node metastases in stations 8a (common hepatic artery), 9 (celiac trunk) and/or 16b1 (aorto-caval) should lead to abandoning of pancreatoduodenectomy, especially in the era of more potent chemotherapy regimens such as FOLFIRINOX. No multicenter prospective study has routinely sampled all these stations.

Study objective

Lymph node metastases in stations 8a (common hepatic artery), 9 (celiac trunk) and/or 16b1 (aorto-caval) should lead to abandoning of pancreatoduodenectomy

Study design

2015: Start PANODE

2015-2019: Inclusion and data collection via the Dutch Pancreatic Cancer Audit

2020: End of study

Intervention

Standard resection and marking of lymph node stations 8a, 9 and 16b1 during resection of pancreatic or peri-ampullary cancer with pancreatoduodenectomy. Each center can follow routine practice and sampling.

Contacts

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Eligibility criteria

Inclusion criteria

- Adult patients (> 18 yrs)
- Pancreatoduodenectomy (either classic Whipple or pylorus preserving) for suspected pancreatic or periampullary malignancy

Exclusion criteria

- Other active malignancy or previous history of any malignancy if not treated with curative intent >5 years previously
- Pregnancy

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 01-10-2015
Enrollment: 700
Type: Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 02-03-2020
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	NL8424
Other	METc AMC : 015.0124

Study results