Intra-operative ultrasound to determine the vascular involvement and resectability of locally advanced and (borderline) resectable pancreatic cancer

No registrations found.

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

Summary

ID

NL-OMON26062

Source Nationaal Trial Register

Brief title ULTRAPANC

Health condition

Pancreatic cancer

Sponsors and support

Primary sponsor: LUMC Source(s) of monetary or material Support: Dutch Cancer Society

Intervention

Outcome measures

Primary outcome

Correlation between preoperative imaging and IOUS regarding the assessment of

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resectability.

Secondary outcome

Change in surgical plan before and after IOUS, correlation between IOUS and pathological examination, resection margin status

Study description

Background summary

Determination of tumor extension and resectability of pancreatic cancer, especially after neoadjuvant chemotherapy, is troublesome on preoperative imaging. The assessment of vascular involvement is particularly important since these are the most affected resection margins, in addition a vascular resection can be performed to aim for a radical resection. The value of intra-operative ultrasound (IOUS) in adequate assessment of tumor extension, vascular involvement and resectability with subsequent IOUS-guided resection has scarcely been studied. This study aims to assess the added value and diagnostic accuracy of IOUS in predicting resectability of pancreatic cancer.

Study objective

Intra-operative ultrasound will change the resectability status in 15% of patients compared with pre-operative CT-scans.

Study design

The study is open for inclusion since November 2018. Expected study duration is 2 years.

Intervention

Intra-operative ultrasound

Contacts

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Eligibility criteria

Inclusion criteria

Patients with pancreatic cancer planned for curative-intended resection, any vascular contact on pre-operative CT-imaging, treated with or without neoadjuvant chemotherapy, aged 18 years or older.

Exclusion criteria

Peri-ampullary cancer of non-pancreatic origin (i.e. duodenal carcinoma, papillary carcinoma, neuro-endocrine tumors or intra-papillary mucinous neoplasms without malignant degeneration)*. Pancreatic cancer in the absence of vascular involvement on (pre-treatment) computed tomography. *When in doubt between cancer malignancy or benign condition, inclusion/registration is allowed based on the rationale that curative-intent resection is also the treatment goal in these patients.

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

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Recruitment status:	Recruiting
Start date (anticipated):	05-11-2018

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Enrollment:	85
Туре:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinionDate:21-03-2019Application 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 NTR-new Other **ID** NL7621 METC LUMC : B18.018

Study results