Staging laparoscopy combined with ultrasonography and near-infrared fluorescence imaging to detect occult pancreatic metastases

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28591

Source
NTR

Health condition

Pancreatic and periampullary cancer

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Dutch Cancer Society

Intervention

Outcome measures

Primary outcome

- Percentage of averted laparotomies.

Secondary outcome

- Sensitivity and positive predictive value of laparoscopic inspection vs. LUS vs. NIR fluorescence imaging vs. histopathological examination.

- Positive and negative predictive value of LUS vs. NIR fluorescence imaging on the occurrence of distant metastases.

- Distant disease-free survival (occurrence of distant metastases)

- Overall survival

- Perioperative morbidity and mortality.

- Duration of surgical procedures.

Study description

Background summary

Even after extensive preoperative assessment, up to 38% of patients undergoing laparotomy with curative intent turn out to have metastases or unresectable disease, preventing curative surgery. Moreover, a substantial number of patients present shortly after surgery with liver metastases that must have been present during surgery, but have not been identified. SL combined with LUS and NIR fluorescence imaging may identify metastases and unresectable disease, sparing patients with incurable disease the morbidity, inconvenience and expense of a futile operation. Staging laparoscopy in pancreatic cancer patients is being advocated in literature, but has not yet been implemented in clinical guidelines.This is a phase II single center, single-arm trial to assess the added value of staging laparoscopy (SL), laparoscopic ultrasonography (LUS) and near-infrared (NIR) fluorescence imaging in patients with pancreatic cancer undergoing resection with curative intent.

Study objective

The yield of staging laparoscopy will be increased by adding laparoscopic ultrasound and laparoscopic near-infrared fluorescence imaging.

Study design

3 months follow-up

Intervention

In addition to standard-of-care, patients will receive an intravenous injection of 10 mg ICG 1-3 days prior to surgery. During surgery, patients undergo a SL, whereupon inspection, LUS and NIR fluorescence imaging will be performed. A biopsy will be taken from any suspect lesions.

Decision to continue the resection is up to the surgeon. Follow-up will last at least 6 months.

Contacts

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Eligibility criteria

Inclusion criteria

- 18 years or older;

- Patients with pancreatic or periampullary cancer undergoing resection with curative intent;

- Stage 2A or higher; or tumor sized 3 cm or more;

- Absence of any psychological, familial sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial;

- Before patient registration, written consent must be given according to ICH/GCP, national and local regulations.

Exclusion criteria

- History of allergy to iodine, shellfish or ICG;

- Pregnant or lactating woman;

- Any condition that in the opinion of the investigator could potentially jeopardize the health status of the patient.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2016
Enrollment:	25
Type:	Anticipated

Ethics review

Positive opinion

Date:	31-07-2017
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	NL6461
NTR-old	NTR6639
Other	Commissie Medische Ethiek van het LUMC : P10.001

Study results