Intra-operatieve fluorescente beeldvorming alvleesklier tumoren en galwegen.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24019

Source
NTR

Brief title
GREEN LIGHT PANCREAS

Health condition

Pancreatic cancer, pancreas, bile ducts

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: Center for Translational Molecular Medicine (CTMM)

Intervention

Outcome measures

Primary outcome

Primary outcome parameter is the number of identified pancreatic tumors.

Secondary outcome

Secundary parameters are the differences in tumor-to-background ratios measured in patients that recieved different amounts of ICG. Furthermore, the fluorescence of bile ducts on different time-points after injection. Another secundary outcome parameter is the lymfatic drainage pattern of a pancreatic tumor.

Study description

Background summary

Pancreatic cancer is the third leading cause of cancer-related death in the United States and Europe. Surgical resection is
the only available curative therapy. During pancreatic surgery, it is often hard to differentiate between malignant tissue and
benign tissue. In over 35% of cases, the resection margins appear to be positive. To reduce the numer of patients with
positive resection margins, near-infrared fluorescence imaging can be very usefull.

Standard Whipple procedure will be performed. During surgery, the near-infrared dye ICG will be injected and the pancreatic carcinoma and extra-hepatic bile ducts will be visualized non-invasively using our experimental camerasystem.

Study objective

Fluorescent near-infrared imaging can accurately detect pancreatic cancer non-invasively during a whipple procedure.

Study design

The primary and secondary outcomes will be assessed during surgery and pathological assessment.

Intervention

Standard Whipple procedure will be performed. During surgery, the near-infrared dye ICG will be injected and the pancreatic carcinoma and extra-hepatic bile ducts will be visualized non-invasively using our experimental camerasystem.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients diagnosed with pancreatic cancer eligible to undergo a curative resection;

2. Age between 18 and 80 years old.

Exclusion criteria

1. No History of allergy to iodine, shellfish, indocyanine green, human serum albumin and/or history of hyperthyroidism or severe renal impairment;

2. Patient pregnant or lactating.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2010
Enrollment:	15
Type:	Actual

Ethics review

Positive opinion

Date:	12-02-2010
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	NL2097

Register	ID
NTR-old	NTR2214
Other	METC LUMC : P10.001
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A