

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

Published: 10-02-2010

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The main objective of this study is to determine the added value of NIR fluorescence imaging in patients with pancreatic cancer undergoing SL and to identify predictors for patients that may benefit from SL.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Endocrine gland therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON43841

Source

ToetsingOnline

Brief title

NIRF stadieringslaparoscopy

Condition

- Endocrine gland therapeutic procedures

Synonym

Pancreatic cancer metastases, secondary malignancies

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Indocyanine green (ICG), Near-infrared fluorescence (NIRF), Pancreatic cancer metastases.

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.
- Quality of life (EORTC QLQ-C30 taken during standard planned outpatient clinic visits every 3 months).

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. By addition of NIR

fluorescence imaging to SL and LUS more metastases might be identified, sparing patients with incurable disease the morbidity, inconvenience and expense of a futile operation.

Study objective

The main objective of this study is to determine the added value of NIR fluorescence imaging in patients with pancreatic cancer undergoing SL and to identify predictors for patients that may benefit from SL.

Study design

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.

Intervention

Intravenous injection of 5 or 10 mg ICG 30 minutes to 24 hours prior to surgery.

Study burden and risks

Patients will be asked to attend to the hospital 1-3 days prior to surgery. They will receive an intravenous injection of 10 mg of ICG. This will take approximately 30 minutes, whereafter patients can go home again.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- 18 years or older;
- Patients with pancreatic or periampullary cancer undergoing staging laparoscopy
- 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;
- Renal impairment, defined as eGFR > 60;
- Patients with hyperthyroidism;
- 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 phase: 2

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	28-02-2010
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO	
Date:	10-02-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	09-02-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	16-04-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	27-07-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 29-11-2012

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 12-02-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 20-02-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 24-09-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 11-02-2014

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 17-04-2014

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 08-10-2014

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 18-12-2014

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 08-04-2015

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 24-11-2015

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 24-08-2016

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

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	NL30732.058.09