

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

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28591

Bron

NTR

Aandoening

Pancreatic and periampullary cancer

Ondersteuning

Primaire sponsor: Leiden University Medical Center

Overige ondersteuning: Dutch Cancer Society

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Percentage of averted laparotomies.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

3 months follow-up

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Sven Mieog
Leiden
The Netherlands

Wetenschappelijk

Sven Mieog
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-01-2016
Aantal proefpersonen:	25
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	31-07-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6461
NTR-old	NTR6639
Ander register	Commissie Medische Ethiek van het LUMC : P10.001

Resultaten