

Minimally invasive, Indocyanine-Guided Metastasectomy in patients with Colorectal Liver Metastases

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NIRF imaging during minimally invasive resection of liver metastases can aid in achieving higher radical resection rates in patients with colorectal liver metastases.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21326

Bron

Nationaal Trial Register

Verkorte titel

MIMIC

Aandoening

Colorectal liver metastases

Ondersteuning

Primaire sponsor: None

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Percentage radical resections

Toelichting onderzoek

Achtergrond van het onderzoek

Radical surgical resection is still seen as the 'gold standard' and the only potential for cure in patients diagnosed with colorectal liver metastases. Currently 5-year survival rates are between 35-60% in patients undergoing surgery with curative intent. Achieving a radical resection (>1mm) shows superior survival in patients undergoing surgery. Therefore, improving radical resection rates has the potential to improve overall survival rates. According to data from the Dutch Hepato Biliary Audit, up to 31% of the patients underwent an 'intention-to-treat' laparoscopic resection in 2016 in the Netherlands. This is expected to increase in the coming years. During laparoscopy the surgeon is limited in both visible and tactile information for determination of the resection margin of colorectal liver metastases (CRLM). Currently, near infrared fluorescent (NIRF) imaging with ICG is used to determine the resection margin in all participating centres as standard-of-care. Surgeons experience this technique with real-time fluorescent overlay laparoscopy as user friendly, and we have seen promising results so far. Although the fluorescent rim is already used for resection margin assessment, the radical resection rates have not been documented before. Due to the accumulation of ICG inside immature hepatocytes surrounding the CRLM, a specific fluorescent 'rim' is present around the metastasis. Preliminary data show these fluorescent rims are present around all CRLM. Therefore, the use of NIRF imaging during laparoscopic resections of CRLM has the potential to increase radical resection rates.

Doel van het onderzoek

NIRF imaging during minimally invasive resection of liver metastases can aid in achieving higher radical resection rates in patients with colorectal liver metastases.

Onderzoeksopzet

Surgery and follow-up

Contactpersonen

Publiek

Leids Universitair Medisch Centrum
Babs Sibinga Mulder

0715265401

Wetenschappelijk

Leids Universitair Medisch Centrum
Babs Sibinga Mulder

0715265401

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

18 years or older

Patients with colorectal liver metastases (primary and recurrent CRLM) planned for curative-intent minimally invasive surgery, either laparoscopic or robotic resection

Patients eligible for indocyanine infusion 24h prior to surgery according to the hospitals protocol

Patients with or without neoadjuvant chemotherapy (for primary and/or secondary colorectal tumor/metastases)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients with contraindications for Indocyanine green:

- o Iodide allergy or allergies for shells and/or clamps

- o Impaired kidney function (eGRF <50)

Local recurrent CRLM at the site of previous ablative therapy

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
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: 01-09-2018
Aantal proefpersonen: 186
Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies
Datum: 09-04-2019
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	NL7674
Ander register	METC LUMC : G18.115

Resultaten