Het beter in beeld krijgen van uitzaaiingen tijdens een HIPEC operatie bij patiënten met dikke darm kanker uitzaaiingen in het buikvlies

Gepubliceerd: 04-04-2016 Laatst bijgewerkt: 19-03-2025

The use of intraoperative imaging techniques will improve sensitivity for detection of peritoneal metastases of colorectal origin

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	-

Samenvatting

ID

NL-OMON27102

Bron
Nationaal Trial Register

Aandoening

peritoneal metastases, peritoneal carcinomatoris, colorectal cancer, imaging techniques, fluorescence, narrow-band imaging, ICG, 5-ALA
peritoneale metastasen, peritonitis carcinmatosa, colorectaal carcinoom, beeldvormende technieken, fluorescentie

Ondersteuning

Primaire sponsor: VU University medical centre
Overige ondersteuning: initiator is sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To evaluate the sensitivity and specificity of Narrow Band Imaging, Near-infrared Indocyanin Green Imaging, 5-ALA fluorescent imaging and Indigo Carmine Blue Spray Dye Chromoendoscopy in the detection of malignant lesions.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The presence of peritoneal metastasis is a poor prognostic factor for patients with colorectal cancer. Without treatment median survival is 3 months. Cytoreductive surgery (CRS) combined with hyperthermic intraperitoneal chemotherapy (HIPEC) improves survival significantly with a median of 22.3 months. Current difficulty is detection of small peritoneal metastases, in order to achieve complete cytoreduction. Enhanced imaging could potentially increase detection rate and improve cytoreduction. Next to high definition endoscopic imaging, other image-enhancement modalities. such as narrow-band imaging (NBI), ‘near-infrared indocyanin green fluorescent imaging’ (NIR-ICG), photodynamic diagnosis with 5-amino levulinic acid (5-ALA) and spray-dye chromoendoscopy (SDCE) can enhance conventional white-light detection and therefore lead to a more complete extent of cytoreduction and better survival.

Objective: Our primary objective is to improve tumour detection rate by using enhanced imaging modalities (NBI, NIR-ICG, 5-ALA and SDCE).

Study design: Safety and feasibility study

Study population: Patients with radiological and/or clinically proven peritoneal carcinomatosis of colorectal origin.

Intervention: Patients undergo exploratory laparoscopy or laparotomy of the regions suspected for malignant lesions by conventional white light, NBI, NIR-ICG, 5-ALA and SDCE, prior to CRS followed by HIPEC. 5-ALA and ICG will not be administered in the same patients.

Main study parameters/endpoints: To evaluate the sensitivity and specificity of tumour detection of these four image enhancement modalities compared to conventional white light.

Reference standard will be the result of the pathological examination of the biopsy.

Doel van het onderzoek

The use of intraoperative imaging techniques will improve sensitivity for detection of peritoneal metastases of colorectal origin

Onderzoeksopzet

intraoperative evaluation

Onderzoeksproduct en/of interventie

Administration of either Indocyanine Green (ICG) or 5-aminolevulinic acid (5-ALA) preoperatively

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Orally and written informed consent

• Age 18 years and older

• Elective cytoreductive surgery followed by HIPEC

• Regular preoperative work-up

• Laparoscopic approach

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Patients who are legally or mentally incapable or unable to give informed consent

• Patients younger than 18 years

• ASA (American Society of Anaesthesiologists) score higher than 3

• Exclusion criteria for cytoreductive surgery followed by HIPEC

• Exclusion criteria for resection of colorectal cancer

• Patients who have had major open abdominal surgery

• Open-close procedure (peritoneal metastases are to vast for resection)

• Hypersensitivity reaction to prior usage of indigo carmine

• Severe high blood pressure, cardiac ischemia and heart insufficiency

• Iodine allergy

• Patients with hyperthyroidism or autonomous hyperthyroid adenoma

• Interaction with any of the following medication: any anticonvulsive medicine, bisulphites, haloperidol, heroin, meperidine, metamizol, methadone, morfine, nitrofurantoine, opiate alkaloids, fenobarbital, fenylbutazon, cyclopropane, probenicid, rifamycin, tetracyclines, sulphonamides, fluoroquinolones and hypericin extracts

• Hypersensitivity reaction to prior usage of indocyanin green injection

• Hypersensitivity to 5-ALA or porphyrins

• Acute or chronic types of porphyria

• Urgent indication for surgery

• Pregnancy

• Chronic kidney failure (eGFR<55)

• Chronic liver failure (ASAT, ALAT, AF or yGT > two times max normal value)

Onderzoeksopzet

Opzet

Onderzoeksmodel: Anders
Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-04-2016
Aantal proefpersonen:	20
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	04-04-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44157

Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5676
NTR-old	NTR5820
CCMO	NL50797.029.15
OMON	NL-OMON44157

Resultaten