Detectie van tumorweefsel met behulp van Bevacizumab-IRDye800CW in combinatie met een optisch beeldvormingssysteem bij patiënten die de HIPEC procedure ondergaan, een haalbaarheidsstudie.

Gepubliceerd: 08-06-2014 Laatst bijgewerkt: 19-03-2025

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

Samenvatting

ID

NL-OMON27201

Bron
NTR

Verkorte titel
HI-LIGHT

Aandoening

VEGF-Targeted Near-Infrared Fluorescence imaging in Peritoneal Carcinomatosis

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Visualization of fluorescent tumor tissue confirmed by ex vivo immunohistochemistry or fluorescence microscopy of excised specimen.

Toelichting onderzoek

Achtergrond van het onderzoek

This project consist of the realization and clinical validation of intraoperative imaging of tumor tissue in peritoneal carcinomatosis of colorectal origin.
By applying a method to assess the extend of peritoneal dissemination of cancer through a novel targeted optical fluorescent imaging methodology staging and resection might be more optimal.

VEGF-A is highly unregulated in colorectal tumortissue and can be targeted by using the VEGF antibody Bevacizumab (Avastin). Bevacizumab can be conjugated to the near infrared fluorphore, 800CW (bevacizumab-IRDye800CW).

In this study 10 patients scheduled for a HIPEC procedure will receive an IV injection with bevacizumab-IRDye800CW two days prior to the procedure.

During the procedure fluorescent tissue will be sampled and will be analyzed by an pathologist. The peritoneal cancer index wil be estimated using the fluorescent signal.

All procedures will be carried out in the University Medical Center Groningen

Onderzoeksopzet

day 1 tracer administration

day 3 operation date

Onderzoeksproduct en/of interventie

Patients scheduled for a HIPEC procedure for peritoneal carcinomatosis of colorectal origin will be consented for this study. There will be three study related visits. During a screening visit (visit 1), eligibility will be evaluated and patient characteristics will be collected. During the second visit 4.5 mg of bevacizumab--IRDye800CW will be administered intravenously. The patient will then be observed for 1 hour post administration. One day after administration of the tracer (visit 3 one day before surgery) the patient is administered to the hospital as in

the standard procedure, or the patient can stay after the tracer injection if this more convenient for the patient. During the HIPEC procedure the fluorescent imaging will be performed and data acquired.

Contactpersonen

Publiek

University Medical Center Groningen
Department of Surgery / BioOptical Imaging Center Groningen

G.M. Dam, van
Hanzeplein 1

Groningen 9700 RB
The Netherlands
+31 (0)50 3612283

Wetenschappelijk

University Medical Center Groningen
Department of Surgery / BioOptical Imaging Center Groningen

G.M. Dam, van
Hanzeplein 1

Groningen 9700 RB
The Netherlands
+31 (0)50 3612283

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-Age ≥ 18 years.

-Patients with histopathological proven peritoneal carcinomatosis from colorectal origin who are
scheduled to undergo the HIPEC procedure

- Patient is considered to be mentally and physically fit for the HIPEC procedure as judged by the responsible physician WHO performance score 0-2

- Signed written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Concomitant malignancies, except for adequately treated basocellular carcinoma of the skin or in situ carcinoma of the cervix uteri. Subjects with prior malignancies must be disease-free for at least 5 years.

- Distance metastasis (liver / lungs)

- Medical or psychiatric conditions that compromise the patient’s ability to give informed consent.

- Concurrent uncontrolled medical conditions.

- Pregnancy or breast feeding.

- Clinically significant (i.e. active) cardiac disease (e.g. congestive heart failure, symptomatic coronary artery disease and cardiac dysrhythmia, e.g. atrial fibrillation, even if controlled with medication) or myocardial infarction within the past 12 months.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2014

Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-06-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40339
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4514
NTR-old	NTR4632
CCMO	NL45588.042.13
OMON	NL-OMON40339

Resultaten