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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27201

Source
NTR

Brief title
HI-LIGHT

Health condition

VEGF-Targeted Near-Infrared Fluorescence imaging in Peritoneal Carcinomatosis

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Improvement of the detection rate of tumor tissue using Multispectral Fluorescence Reflectance Imaging (MFRI) by calculation the Peritoneal Carcinomatosis Index (PCI).

Study description

Background summary

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

Study design

day 1 tracer administration

day 3 operation date

Intervention

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.

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Eligibility criteria

Inclusion criteria

-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.

Exclusion criteria

- 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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2014
Enrollment:	10

Type:	Anticipated

Ethics review

Positive opinion
Date: 08-06-2014

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40339
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results