Liquid biopsies in patients with peritoneal metastases of colorectal cancer.

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Primary Objective: - To evaluate the detection of circulating tumor DNA (ctDNA) in patients with peritoneal metastases (PM) of colorectal origin undergoing cytoreductive surgery and hyperthermic intraperitoneal chemohterapy (HIPEC) at time of...

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

Samenvatting

ID

NL-OMON22788

Bron
NTR

Verkorte titel
LIBEC

Aandoening

peritoneal metastases (PM), colorectal cancer (CRC), cytoreductive surgery and hyperthermic intraperitoneal chemotherapy (HIPEC), liquid biopsy, circulating tumor DNA (ctDNA)
Dutch: peritoneale metastasen (PM), colorectaal carcinoom (CRC), cytoreductie en hypertherme intraperitoneale chemotherapie (HIPEC), liquid biopsy, circulerend tumor DNA (ctDNA)

Ondersteuning

Primaire sponsor: VU medisch centrum
Afdeling Heelkunde
Boelelaan 1117
1081 HV, Amsterdam
Overige ondersteuning: VU medisch centrum
Afdeling Heelkunde

Boelelaan 1117
1081 HV, Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Plasma levels of ctDNA preoperatively.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Patient selection and follow-up after cytoreductive surgery and HIPEC (Hyperthermic IntraPEritoneal Chemotherapy) for peritoneal metastases (PM) of colorectal origin are hampered by limitations of diagnostic modalities. Conventional radiological imaging has a low sensitivity for detection of peritoneal metastases and is unable to detect the extensiveness of the disease. The HIPEC procedure is significantly more effective in early disease but unfortunately due to limitations of tests peritoneal metastases are often diagnosed in an advanced stage, limiting treatment options. Circulating tumour DNA (ctDNA) in plasma (also called: Liquid Biopsies) has shown promising preliminary results for diagnosis and follow-up of patients with colorectal cancer. The use of ctDNA could potentially improve detection of PM, improve patient selection for HIPEC and possibly detect recurrent disease during follow-up at an earlier stage. Currently the ctDNA tests have not been evaluated in patients with PM.

Objective: To evaluate feasibility of ctDNA detection in patients with PM undergoing cytoreductive surgery and HIPEC.

Study design: Prospective feasibility study

Study population: Patients with known PM and planned to undergo cytoreductive surgery and HIPEC for PM of colorectal origin.

Intervention (if applicable): Not applicable

Main study parameters/endpoints: Main study parameter is the presence of detectable mutated ctDNA in the patient’s plasma at time of diagnosis. Secondly the quantity is evaluated after cytoreductive therapy 2-4 weeks postoperatively to evaluate treatment effect.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

This study has no benefits for the patient. Also participation does not add any burden or risks, other than the minor complications related to venapunction. These include: hematoma or puncture related anxiety.

Doel van het onderzoek

Primary Objective:

- To evaluate the detection of circulating tumor DNA (ctDNA) in patients with peritoneal metastases (PM) of colorectal origin undergoing cytoreductive surgery and hyperthermic intraperitoneal chemohterapy (HIPEC) at time of diagnosis in a feasibility trial (N=20 patients).

Secondary Objective:

- To evaluate a potential decrease of levels of ctDNA decrease after cytoreductive surgery and HIPEC

Feasibility; The study is feasible if the following criteria are met

1. If in at least 70% of the patients ctDNA status correlates with mutational status of the tissue specimen preoperatively (qualitative)

2. If at least 50% of the patients with detectable mutated ctDNA show decreased levels of ctDNA after treatment (quantitative)

Onderzoeksopzet

Plasma levels of ctDNA preoperatively: day of HIPEC surgery, prior to surgery.

Plasma levels of ctDNA postoperatively: 2-4 weeks after HIPEC surgery.

Onderzoeksproduct en/of interventie

This is an observational cohort study to assess the correlation between ctDNA and cytoreductive surgery. No interventions are performed.

Treatment and follow-up of patients will not be influenced by ctDNA results.

Two additional viles of blood (2*9mL Streck) are taken before (on the day of HIPEC surgery) and after cytoreductive surgery and HIPEC (2-4 weeks after HIPEC surgery).

Contactpersonen

Publiek

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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

- Peritoneal metastases only

- Regular preoperative work-up

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

- Presence of liver metastases on CT-scan/peroperatively

- Presence of pulmonary metastases on CT-scan/peroperatively

- Anxiety for vena puncture

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	29-08-2016
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-04-2018

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43017
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6960
NTR-old	NTR7148
CCMO	NL57226.029.16
OMON	NL-OMON43017

Resultaten

Samenvatting resultaten
After completion of the study and analysis of the data results will be made public without restriction, independent of the outcome. They will be submitted for publication to an international peer-reviewed journal. The principle investigators and study coordinators will prepare the manuscript together with those who substantially contributed to the study.