Liquid biopsies in patients with peritoneal metastases of colorectal cancer.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22788

Source
NTR

Brief title
LIBEC

Health condition

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)

Sponsors and support

Primary sponsor: VU medisch centrum
Afdeling Heelkunde
Boelelaan 1117
1081 HV, Amsterdam
Source(s) of monetary or material Support: VU medisch centrum
Afdeling Heelkunde
Boelelaan 1117
1081 HV, Amsterdam

Intervention

Outcome measures

Primary outcome

Plasma levels of ctDNA preoperatively.

Secondary outcome

Plasma levels of ctDNA postoperatively.

Study description

Background summary

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.

Study objective

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)

Study design

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

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

Intervention

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).

Contacts

Public
Department of Surgery, VU University Medical Center

Nina R Sluiter
De Boelelaan 1117

Amsterdam 1081 HV
The Netherlands
+31 (0)20 4445234
Scientific
Department of Surgery, VU University Medical Center

Nina R Sluiter
De Boelelaan 1117

Amsterdam 1081 HV
The Netherlands
+31 (0)20 4445234

Eligibility criteria

Inclusion criteria

- Orally and written informed consent

- Age 18 years and older

- Elective cytoreductive surgery followed by HIPEC

- Peritoneal metastases only

- Regular preoperative work-up

Exclusion criteria

- 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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-08-2016
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-04-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43017
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
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.