A pilot study investigating the possibility to detect cancer DNA in the blood of cancer patients

No registrations found.

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

Summary

ID

NL-OMON22021

Source
NTR

Brief title
NICT

Health condition

Breast Cancer
Colorectal Cancer
Glioma
Non-small Cell Lung Cancer

Sponsors and support

Primary sponsor: Maastricht University Medical Center (MUMC)
Source(s) of monetary or material Support: Fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Demonstrate the presence or absence of ctDNA in patient’s plasma

Secondary outcome

Examine if there is a sufficient concentration of ctDNA in the plasma to reliably diagnose cancer and determine the CNV

Comparison with tumor DNA isolated from the tumor of the patient

Study description

Background summary

Rationale: Genetic, epigenetic and genomic alterations are key elements in tumourigenesis. Tumour cells become aneuploid and/or may show loss or gain of (parts of) chromosomes. It is known that tumours shed cell free DNA into the blood circulation of the patient, called cell-free tumour DNA (ctDNA). Recent studies show that non-invasive prenatal testing (NIPT), which is used for detecting fetal chromosomal trisomy 21, 13, 18 (and other aneuploidies as an incidental finding), in the circulation of the pregnant woman, may also detect ctDNA. The detection of ctDNA has led to discordant results between the NIPT and invasive prenatal diagnostics in pregnant women which were later diagnosed with an (occult) malignancy. This finding raised the question whether or not the NIPT methodology can be applied for detecting ctDNA in cancer patients. Furthermore, we wonder if it would be possible to determine a genetic profile of the tumour using ctDNA obtained from one blood drawing by venipuncture. The Cytogenetic laboratory of the department of Clinical Genetics in Maastricht offer NIPT in a diagnostic setting a part of a nationwide NIPT evaluation study (TRIDENT) in the Netherlands. Few studies have explored the possibilities of so-called non-invasive cancer testing (NICT), but none of them used the NIPT methodology and all studies focus on a small subgroup of cancer patients.
In this pilot study, we investigate the feasibility of NICT by NIPT methodology to detect ctDNA in patients with different types of cancer. We will contribute new insights in non-invasive cancer testing and its application in various types of cancer.

Objective: To test if our NIPT approach is capable of detecting ctDNA in patients diagnosed with four different types of cancer.

Study design: This study is a cross-sectional pilot study in which we aim to demonstrate that our NIPT approach can detect ctDNA representative for the cancer of the patients. Non-

invasive cancer testing (NICT) will be performed in parallel to current standard diagnostics for genetic tumour profiling. This latter aspect is not part of this study.

Study population: Patients > 18 years with a newly diagnosed malignancy of the breast, colon, lung or glioma.

Main study parameters/endpoints: NICT chromosome aneuploidy profile that is representative for the primary type of tumour .

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Minimal burden: one moment of blood sampling for the patient during a regular follow-up visit. In most cases the extra blood sampling will be combined with regular blood sampling. Benefit: no benefit for the patient.

Study objective

The objective of the study is to test the feasibility of non-invasive untargeted low-coverage WGS with WISECONDOR z-score analysis for the detection of plasma ctDNA in patients diagnosed with cancer. The second objective is to genotype the ctDNA and map the CNVs of the cancer patients. This will be a pilot study without a control group.

Study design

There is one timepoint on which all measurements will be conducted.

Intervention

No intervention is used

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with newly diagnosed local or metastatic breast cancer, colorectal cancer, non-small cell lung cancer and anaplastic glioblastoma, before start of radiation therapy, chemoradiation or chemotherapy.

2. Patients age > 18 years, willing and able to comply with the protocol as judged by the investigator with a signed informed consent

Exclusion criteria

1. Patients with a history of malignant disease other than the disease under study, with an exception for adequately treated squamous cell carcinoma of the skin, basal cell carcinoma of the skin and in situ cervix carcinoma.

2. Pregnancy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2016
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-02-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50225
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5569
NTR-old	NTR5691
CCMO	NL55080.068.15
OMON	NL-OMON50225

Study results