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

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

Samenvatting

ID

NL-OMON22021

Bron
NTR

Verkorte titel
NICT

Aandoening

Breast Cancer
Colorectal Cancer
Glioma
Non-small Cell Lung Cancer

Ondersteuning

Primaire sponsor: Maastricht University Medical Center (MUMC)
Overige ondersteuning: Fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

No intervention is used

Contactpersonen

Publiek

Department of Clinical Genetics

C.E.M. de Die-Smulders
Maastricht University Medical Centre P.O. Box 5800

Maastricht 6202 AZ
The Netherlands
Phone: +31 (0)43 387 7859

Wetenschappelijk

Department of Clinical Genetics

C.E.M. de Die-Smulders
Maastricht University Medical Centre P.O. Box 5800

Maastricht 6202 AZ
The Netherlands
Phone: +31 (0)43 387 7859

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel

Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2016
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-02-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50225
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten