Circulating tumor DNA in urothelial cancer.

Gepubliceerd: 08-07-2014 Laatst bijgewerkt: 18-08-2022

To dermine the kinetics and spectrum of tumor mutations in the urine and plasma of bladder cancer patients receiving neoadjuvant chemotherapy for locally advanced cancer or systemic therapy for metastatic disease.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24518

Bron
NTR

Aandoening

Urothelial cancer -Blaaskanker

Ondersteuning

Primaire sponsor: The Netherlands Cancer Institute- Antoni van Leeuwenhoek
Overige ondersteuning: Fund

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To explore the longitudinal kinetics of tumor mutations in the urine and plasma of bladder cancer patients receicing systemic therapy fo locally advanced cancer or metastatic disease.

Toelichting onderzoek

Achtergrond van het onderzoek

Study design:

Plasma, urine and tumor specimens will be prospectively collected to determine the longitudinal kinetics of cancer mutations in bladder cancer during chemotherapy and at relapse. In addition, material collected in this study will be used to optimize the analysis of ctDNA in our institute and to establish this technique at the NKI/AVL.

Study population:

The target population consists of patients who have suspected or confirmed urothelial cell cancer of the bladder or urinary tract and who will be treated with systemic therapy. In addition, a small number of patients with non-muscle invasive cancer will be included as controls.

Main study parameters/endpoints:

Primary endpoint:

-The longitudinal kinetics of the spectrum of tumor mutations in the urine and plasma of bladder cancer patients receiving systemic therapy.

-To explore the predictive value of changes in urine cfDNA and plasma ctDNA for treatment outcome (progression free survival and pathological response rate) of neoadjuvant chemotherapy for bladder cancer

Doel van het onderzoek

To dermine the kinetics and spectrum of tumor mutations in the urine and plasma of bladder cancer patients receiving neoadjuvant chemotherapy for locally advanced cancer or systemic therapy for metastatic disease.

Onderzoeksopzet

Radiological evaluation: patients will be evaluated according to local clinical practice:

During neoadjuvant treatment:

- Initial clinical staging: physical exam, TUR or bladder biopsy, FDG-PET CT thorax/abdomen/pelvis.

-After 2 cycles to determine tumor response:
Physical exam, cystoscopy and CT
thorax/abdomen/pelvis-scan

-After 4 cycles (CT/FDG-PET)

-6 and 12 months after cystectomy

For metastatic disease: after 3 cycles of therapy by CT-scan.

Response evaluation will be assessed according to RECIST version 1.1 guidelines.25

Clinical evaluation: patients will be seen according to standard of care:

During neoadjuvant treatment before each cycle of chemotherapy to assess treatment toxicity
and response to treatment. After cystectomy every 3 months in the first year and every 6 months in the second year to assess disease control. If clinically indicated, further radiological
or metabolic response evaluation will be done.

Onderzoeksproduct en/of interventie

- Peripheral blood samples

- Urine samples

- Tumor biopties

Contactpersonen

Publiek

Nederlands Kanker Instituut/Dutch Cancer Institute
M.S. Heijden, van der
Amsterdam
The Netherlands
+31 20 512 6973

Wetenschappelijk

Nederlands Kanker Instituut/Dutch Cancer Institute
M.S. Heijden, van der
Amsterdam
The Netherlands
+31 20 512 6973

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Indication for systemic treatment with anti-cancer agents in patients with urothelial cancer.

- WHO performance status 0-2

- age > 18yr

- Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Coleection of tissue from a metastatic or primary lesion is not possible.

- Pure non-urothelial carcinoma (SCC/Adenocarcinoma) of the bladder or urinary tract

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2014
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4538
NTR-old	NTR4681
Ander register	NKI-AVL : N13KCM

Resultaten