Circulating tumor DNA in urothelial cancer.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24518

Source
NTR

Health condition

Urothelial cancer -Blaaskanker

Sponsors and support

Primary sponsor: The Netherlands Cancer Institute- Antoni van Leeuwenhoek
Source(s) of monetary or material Support: Fund

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

- To determine the detectability rate and range in levels ctDNA in plasma before start of treatment

- To explore the correlation of levels of ctDNA in plasma with tumor burden

- To explore the correlation between radiological response and urine ctDNA and plasma ctDNA kinetics during and following treatment

- To explore the prognostic value of urine ctDNA and plasma ctDNA for treatment outcome (progression free survival) of neoadjuvant chemotherapy for bladder cancer

- To explore the range and frequency of mutations found in ctDNA, urine ctDNA and tumor samples in bladder cancer.

- Build a biobank of longitudinally collected bladder cancer samples for translational research.

Study description

Background summary

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

Study objective

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.

Study design

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.

Intervention

- Peripheral blood samples

- Urine samples

- Tumor biopties

Contacts

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

Eligibility criteria

Inclusion criteria

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

- WHO performance status 0-2

- age > 18yr

- Written informed consent

Exclusion criteria

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

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

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2014
Enrollment:	80
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results