Tumor-derived circulating endothelial cells as a biomarker in locally advanced and metastatic clear cell renal cell carcinoma

No registrations found.

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

Summary

ID

NL-OMON25402

Source
NTR

Brief title
RECEC

Health condition

Clear cell renal cell carcinoma, endothelial cell, metastatic disease, VEGFR-TKI

Sponsors and support

Primary sponsor: Erasmus MC Medical Center
Source(s) of monetary or material Support: Erasmus MC Medical Center

Intervention

Outcome measures

Primary outcome

The value of CD276-positive CECs in locally advanced or metastatic clear cell renal cell

caricnoma before start VEGFR-TKI based therapy

Secondary outcome

- The association of CD276-positive CEC count in locally advanced or metastatic clear cell renal cell carcinoma with PFS at 12 months

- The association of changes after 4 weeks of VEGFR-TKI treatment in CD276-positive CEC count in locally advanced or metastatic clear cell renal cell carcinoma with PFS at 12 months

Study description

Background summary

Renal cell carcinoma accounts for 2-3% of the malignancies in adults worldwide. 70-80% of the malignant solid lesions of the kidney are clear cell renal cell carcinomas (ccRCC). With ccRCC being relatively chemotherapy and radiotherapy resistant, targeted therapies are the therapies of choice in ccRCC when treatment is indicated. No sensitive biomarkers are available to determine the response of these targeted therapies. Since all of the first-line targeted therapies exert anti-angiogenic effects, circulating endothelial cells (CECs) can fulfill a role in this need for biomarkers. CECs are endothelial cells that are shed from the vessel wall. Recently, we identified a marker (CD276) that can distinguish between CECs that originate from the normal vasculature (CD276-negative) and the tumor vasculature (CD276-positive) in patients. Also, studies have shown that 95-98% of the immunohistochemically stained ccRCC vasculature specimens are positive for CD276 and that diffuse vascular CD276-expression was associated with poor outcome. Therefore, we hypothesize that CD276-positive CECs can be of clinical value in patients with locally advanced metastatic ccRCC.

Study objective

We hypothesize that CD276-positive CECs can be of clinical value in patients with locally advanced or metastatic ccRCC

Study design

- CD276-positive CEC count at baseline and after 4 weeks of VEGFR-TKI based therapy

- PFS at 12 months

Intervention

Blood draw at baseline and after 4 weeks

Contacts

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Eligibility criteria

Inclusion criteria

- Patients with locally advanced or metastatic clear cell renal cell carcinoma

- Candidate for receiving first-line therapy with sunitinib or pazopanib

- Age >18 years

- Written informed consent

Exclusion criteria

- Serious illness or medical unstable condition prohibiting adequate treatment and follow-up

- Previous treatment with systemic therapy for clear cell renal cell carcinoma

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-12-2016
Enrollment:	75
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-06-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45737
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7058

Register	ID
NTR-old	NTR7296
CCMO	NL58598.078.16
OMON	NL-OMON45737

Study results