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

Published: 25-10-2016
Last updated: 15-05-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON45737

Source
ToetsingOnline

Brief title
RECEC study

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
clear cell renal cell carcinoma, kidney cancer

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: circulating endothelial cells, metastatic clear cell renal cell carcinoma

Outcome measures

Primary outcome

The primary endpoint is to explore if the presence of CD276-positive CECs in locally advanced or metastatic ccRCC patients before the start of VEGFR-TKI based therapy, is worth more investigation.

Secondary outcome

Secondary endpoints are to explore whether a CEC count * 8 CD276-positive CECs for start of the therapy is associated with the PFS at 12 months. Furthermore, we will explore if changes in the CD276-positive CEC count measured 4 weeks after start of first-line VEGFR-TKI based therapy are associated with the 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 in 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 CEC 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 or metastatic ccRCC.

Study objective

The primary objective is to explore if the presence of CD276-positive CECs in locally advanced or metastatic ccRCC patients treated with systemic therapy is worth more investigation. Furthermore, the clinical value of CD276-positive CECs will be explored.

Study design

multi-center prospective, open study.

Study burden and risks

in all patients, 2x 10 mL blood for CEC enumeration and characterization will be drawn during another blood draw that is already required for standard care. Therefore, no risks are associated with participation in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Patients with locally advanced or metastatic ccRCC
* 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 ccRCC

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2016
Enrollment:	75

Type:	Anticipated

Ethics review

Approved WMO Date:	25-10-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-03-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25402
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL58598.078.16
OMON	NL-OMON25402