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

Gepubliceerd: 21-06-2018 Laatst bijgewerkt: 15-05-2024

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

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

Samenvatting

ID

NL-OMON25402

Bron
Nationaal Trial Register

Verkorte titel
RECEC

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus MC Medical Center
Overige ondersteuning: Erasmus MC Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The value of CD276-positive CECs in locally advanced or metastatic clear cell renal cell caricnoma before start VEGFR-TKI based therapy

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

- PFS at 12 months

Onderzoeksproduct en/of interventie

Blood draw at baseline and after 4 weeks

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	16-12-2016
Aantal proefpersonen:	75
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-06-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45737
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7058
NTR-old	NTR7296
CCMO	NL58598.078.16
OMON	NL-OMON45737

Resultaten