

Renal toxicity during cancer treatment with angiogenesis inhibitors

Gepubliceerd: 09-06-2015 Laatste bijgewerkt: 18-08-2022

We hypothesize that podocyturia is an early marker of ongoing renal damage during angiogenesis inhibition.

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

Samenvatting

ID

NL-OMON29589

Bron

Nationaal Trial Register

Aandoening

Podocyturia as a possible early marker of renal toxicity during angiogenesis inhibition

Ondersteuning

Primaire sponsor: Dr. M.H.W. Kappers, Amphia hospital Breda

Overige ondersteuning: Stichting Mitialto, Roche

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Incidence of podocyturia during treatment with an angiogenesis inhibitor

Toelichting onderzoek

Doel van het onderzoek

We hypothesize that podocyturia is an early marker of ongoing renal damage during angiogenesis inhibition.

Onderzoeksopzet

Cross-sectionally during treatment with an angiogenesis inhibitor or chemotherapy a spot urine sample will be collected once.

Onderzoeksproduct en/of interventie

Sixty patients treated with an anti-VEGF monoclonal antibody or RTKI at the department of Oncology of the Amphia hospital will be invited to participate in our study. During a routine visit at the outpatient clinic a morning spot urine sample will be collected cross-sectionally during treatment to measure podocyturia. Also blood pressure will be measured.

Furthermore, patients characteristics will be collected. Since treatment with an angiogenesis inhibitor is often combined with chemotherapy, in a comparable group of 20 patients treated with this chemotherapy without an angiogenesis inhibitor, urine samples will be collected to assess podocyturia (= control group 1). Likewise, podocyturia will be determined in 10 'healthy' (control) subjects who visit the outpatient clinic for other medical issues (e.g. analysis of fatigue, abdominal pain, etc. [= control group 2]).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients with malignancy treated with an anti-VEGF monoclonal antibody or receptor tyrosine kinase inhibitor (RTKI) + chemotherapy
- Patients treated with chemotherapy alone (without an anti-VEGF monoclonal antibody or RTKI) = control group 1
- 'Healthy' patients without malignancy and normal kidney function (MDRD > 60 ml/min) without proteinuria (see also exclusion criteria) = control group 2

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Healthy controls (control group 2) with abnormal kidney function and/or proteinuria (protein-to-creatinine ratio > 45 mg/mmol or albumin-to-creatinine ratio > 30 mg/mmol)
- Known renal insufficiency (MDRD < 60 ml/min) in patients with malignancy and/or proteinuria (protein-to-creatinine ratio > 45 mg/mmol or albumin-to-creatinine ratio > 30 mg/mmol) if this latter has been previously reported
- Previous therapy with an anti-VEGF monoclonal antibody or RTKI
- Concomitant chemotherapy frequently associated with renal injury (>10% of patients), e.g. cisplatin

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel: Parallel
Controle: N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestopt
(Verwachte) startdatum: 01-01-2014
Aantal proefpersonen: 90
Type: Werkelijke startdatum

Ethische beoordeling

Positief advies
Datum: 09-06-2015
Soort: Eerste indiening

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
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NTR-new	NL5112
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NTR-old	NTR5244
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Ander register METC has approved the project, but did not assign an ID : MHWK01

Resultaten