Longitudinal analysis of RCC-specific immunity in renal cell carcinoma patients

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Ethical review	Approved WMO
Status	Pending
Health condition type	Renal disorders (excl nephropathies)
Study type	Interventional

Summary

ID

NL-OMON45138

Source
ToetsingOnline

Brief title
Analysis of RCC-specific immunity in RCC patients

Condition

- Renal disorders (excl nephropathies)

Synonym
hypernephroma, kidney cancer

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: immunity, longitudinal, RCC, renal cell carcinoma

Outcome measures

Primary outcome

To study the longitudinal effects of treatment (e.g. anti-CTLA4, BRAF inhibition, and other treatments) for advanced stage renal cell carcinoma on tumor material obtained by surgical removal/biopsies and on peripheral blood components.

To find predictive markers and/or prognostic markers in biopsied tumor material and peripheral blood

To improve current TIL expansion protocols

Secondary outcome

Not applicable.

Study description

Background summary

The treatment of metastatic renal cell carcinoma has experienced a clear improvement in the last couple of years. Targeted treatment, such as TKIs or mTOR inhibitors, achieved in many patients responses of 1-2 years. Unfortunately, with these treatments a total cure can not be achieved. Immunotherapy, such as IFN or IL-2, has lower response rates, but when the patient responds it may be long-term (several years), and often the patient is fully healed. Because of the low response probability, these therapies are not standard in the treatment of RCC. Adoptive cell therapy in melanoma patients has a high response rate which is possibly durable. ACT or T cell checkpoint blockade therapies (eg, ipilimumab, anti-PD-1) are promising and can probably

also stabilize the responses in RCC patients.

Study objective

The aim of this study is to find possible biomarkers (predictive or prognostic) for the treatment of patients with advanced renal cell carcinoma. This will require that changes in the tumor and peripheral blood components are studied before and during the treatment of RCC.
For these analyses, both tumor tissue and peripheral blood samples of RCC patients are needed. These samples will be used for 1) analysis of mechanisms of resistance to treatment with targeted agents such as VEGF (R) and / or mTOR inhibitors and other drugs, 2) finding new targets predictive of response to treatment, and 3) changes in the immune system during immunotherapy like anti-CTLA4 or anti-PD-1/PD-L1 and other resources.

Study design

150 patients are asked to provide blood and tumor tissue to allow further translational research in the laboratory.

Intervention

At some time points blood and biopsies will be taken.

Study burden and risks

The blood tests have no serious risks. The biopsies can cause bleeding or infection.

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

Histologically or cytologically proven renal cell carcinoma
Measurable metastatic lesion(s), according to RECIST 1.1 criteria
Metastatic lesion(s) of which a histological biopsy can safely be obtained
Age above 18 years
Performance score: WHO 0, 1 or 2
Written informed consent

Exclusion criteria

see inclusion criteria

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2012
Enrollment:	600
Type:	Anticipated

Ethics review

Approved WMO Date:	21-11-2012
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	09-05-2017
Application type:	Amendment
Review commission:	METC NedMec

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
CCMO	NL41815.031.12