Biomarkers for Angiogenesis in Renal Cell Carcinoma and Neuro-endocrine Tumours.

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To analyse the concentration catecholamines in thrombocytes of patients with clear cell renal cell carcinoma and low grade neuroendocrine tumours. To compare these concentrations with the concentrations catecholamines in thrombocytes of healthy…

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

Summary

ID

NL-OMON35791

Source
ToetsingOnline

Brief title
Biomarkers for Angiogenesis in Renal Cell Carcinoma and NET.

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: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Angiogenesis, Biomarkers, Neuro-endocrine Tumours, Renal Cell Carcinoma

Outcome measures

Primary outcome

Difference in concentrations DA and 5-HT in thrombocytes of patients with clear cell renal cell carcinoma and healthy controls, and patients with low grade neuroendocrine tumours and healthy controls.

Secondary outcome

Difference in concentrations DA and 5-HT in thrombocytes of patients with clear cell renal cell carcinoma and low grade neuroendocrine tumours before start of a treatment cycle and during a treatment cycle.

Study description

Background summary

The growth of renal cell carcinoma and neuroendocrine tumours depends on angiogenesis. Vascular Endothelial Growth Factor (VEGF) has a stimulating role in angiogenesis and catecholamines probably have a regulating role in angiogenesis. Serotonine (5-HT) stimulates angiogenesis. Yet, the netto-effect of dopamine (DA) is unknown; activation of the DA receptor D1 stimulates angiogenesis, but on the other hand activation of the DA receptor D2 inhibits angiogenesis. These catecholamines are stored in the granules of thrombocytes. Our hypothesis is that the concentration catecholamines in thrombocytes of patients differ from the concentrations catecholamines in thrombocytes of healthy controls.
Angiogenesis inhibitors and mTOR inhibitors are the standard treatment of patients with renal cell carcinoma, and in the future will be the standard treatment of patients with neuroendocrine tumours. Because this medication influences angiogenesis, we want to investigate whether the concentration DA and 5-HT in thrombocytes differs between patients before start of a treatment cycle and during a treatment cycle.

Study objective

To analyse the concentration catecholamines in thrombocytes of patients with clear cell renal cell carcinoma and low grade neuroendocrine tumours. To compare these concentrations with the concentrations catecholamines in thrombocytes of healthy controls. To analyse the concentration catecholamines in thromocytes of patients with clear cell renal cell carcinoma and patients with low grade neuroendocrine tumours before start of a treatment cycle and during a treatment cycle.

Study design

This is a crossectional study. We obtain 10 mL blood of 20 patients with renal cell carcinoma and 20 patients with a neuroendocrine tumour. The blood is drawn twice: once during a treatment cycle with angiogenesis inhibitors or mTOR inhibitors, and once before start of a treatment cycle. We will use this blood to isolate thrombocytes and to measure the concentration catecholamines in these thrombocytes. The concentration catecholamines in thrombocytes of the healthy controls are available.

Study burden and risks

Blood samples will be obtained from the patients during routine check at the outpatient clinic, when blood will be obtained for the follow-up. The methods used are minimal invasive and no serious adverse effects of this procedure is known.
In the future, we hope that the concentrations catecholamines in thromocytes can be used as biomarkers for treatment response and control on efficacy of the treatment.

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

1. Age 18 years or older
2. Patients with clear cell renal cell carcinoma with metastases or patients with a low-grade neuro-endocrine tumor with metastases
3. Written informed consent

Exclusion criteria

1. Use of L-dopa or SSRI
2. Patients with a second primary malignancy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	12-07-2011
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	06-07-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL35885.042.11