Watchful waiting in patients with good and intermediate risk metastatic renal cell carcinoma; an imaging guided observational approach

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ObjectivesPrimary objective: To assess the added value of FDG-PET and 89Zr-Girentuximab-PET results measured at presentation to predict time to progression under watchful waiting in patients with good or intermediate prognosis mccRCC who are...

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-OMON44854

Source
ToetsingOnline

Brief title
IMPACT - Renal Watch

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
kidney cancer, renal cell cancer, Renal cell carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: KWF / Alpe d'HuZes

Intervention

Keyword: Imaging, Renal cell carcinoma, Treatment choice, Watchful waiting

Outcome measures

Primary outcome

Primary endpoint: time to mccRCC progression under watchful waiting as assessed by CT-scans (2, 4, 6, 9, 12 months in year 1 and thereafter every 4 months until progressive disease) criteria.

Secondary outcome

Secondary aims and endpoints

a) To evaluate patient therapy choice, satisfaction and quality of life at 2, 4, 6, 9, 12 months during watchful waiting.

b) To assess quality of life every three months during therapy.

c) To assess treatment response at 3 months following any treatment according to RECIST1.1 criteria using CT-scans.

d) To assess the progression free survival defined as the period between study entry and documented progressive disease within the watchful waiting period.

e) To assess the treatment related progression free survival defined as the time from the start of one of the treatments until the moment of documented tumor progression according to RECIST1.1 or death.

f) To assess overall survival, defined as the period between study entry and death.

g) To correlate baseline PET measurements with PFS following any treatment.

h) To correlate histology, immunology, biomarkers and germline characteristics with natural behaviour of the tumor during the watchful waiting period, and with treatment response following any treatment.

i) To evaluate long term steady state levels of pazopanib or sunitinib with regard to response duration on treatment.

j) To correlate CAIX status of the tumors with 89Zr-girentuximab uptake.

k) time to mccRCC progression under watchful waiting as assessed by CT-scans (2, 4, 6, 9, 12 months in year 1 and thereafter every 4 months until progressive disease) criteria. Rapid progression is defined as PD within 2 months and prolonged indolent disease as SD for >= 1 year after the baseline scans.

Study description

Background summary

Rationale
In part of the patients with good and intermediate risk metastatic renal cell carcinoma (RCC) the disease course is indolent and immediate start of systemic therapy is not necessary. By now, we are not able to identify those patients with indolent disease and the minor group of patients with rapidly progressive disease. In patients with indolent disease, a watchful waiting period is preferred, since their quality of life will not be unnecessary hampered by adverse events and therapy resistance is not induced. This study aims to identify those patients for whom a watchful waiting period is possible by molecular imaging. Furthermore several types of systemic therapy are possible once the progression is proven. These systemic treatments are comparable in terms of efficacy, but not in terms of toxicity and their impact on quality of life.

Study objective

Objectives
Primary objective: To assess the added value of FDG-PET and 89Zr-Girentuximab-PET results measured at presentation to predict time to progression under watchful waiting in patients with good or intermediate prognosis mccRCC who are eligible for watchful waiting.

Study design

Study design
This is a multicenter non-blinded prospective observational study in 40 good and intermediate prognosis mccRCC patients.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness
At baseline, a 18F-FDG-PET-CT and 89Zr-Girentuximab-PET will be performed. During the watchful waiting period CT*s will be made. During therapy, follow-up will include standard laboratory analysis, and CT-scans on regular visits to the outpatient clinic. Side effects of the medication and adverse events as a consequence of the tumor biopsies may occur. The radiation exposure of both PET investigations is acceptable and requires no shielding after injection of 89Zr-labelled girentuximab. Patients may benefit from disease regression or stabilization. All three treatment choices has proven clinical benefit in this patient population.

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

- Able to provide written informed consent
- Age >= 18 years
- Histological or cytological documented RCC with a clear cell component
- Good or intermediate prognosis, defined as none (good risk) or 1-2 (intermediate risk) of the below mentioned risk factors (6):
o Karnofsky performance <80
o Time from diagnosis detection of metastases < 1 year
o Haemoglobin < lower limit of normal (LLN)
o Corrected calcium > upper limit of normal (ULN)
o Neutrophils > ULN
o Platelets > ULN
- A watchful waiting period for 2 months is considered an option according to treating medical oncologist
- No prior systemic treatment for RCC (also non-adjuvant)

Exclusion criteria

- Untreated central nervous system metastases, or symptomatic intracerebral metastases.
- Pregnant or breast feeding women.
- Any serious and/or unstable pre-existing medical, psychiatric, or other condition that would make the subject inappropriate for study participation including any serious condition that could interfere with subject*s safety, provision of informed consent, or compliance with study procedure.

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):	02-02-2015
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	15-11-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-07-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-02-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-12-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-01-2016

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-04-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-07-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL44748.091.13