Everolimage. 89Zr-bevacizumab PET imaging in patients with Renal Cell Carcinoma treated with everolimus; a pilot study.

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

Summary

ID

NL-OMON36512

Source
ToetsingOnline

Brief title
Everolimage.

Condition

- Renal and urinary tract neoplasms benign
- Renal disorders (excl nephropathies)

Synonym
kidney cancer, renal cell carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: grant van farmaceutische industrie voor de scans en ter beschikking stelling van everolimus,Novartis

Intervention

Keyword: biomarker, mTOR inhibition, renal cell carcinoma, VEGF imaging

Outcome measures

Primary outcome

The primary endpoint is change in 89Zr-bevacizumab uptake in tumor lesions

between the baseline scan and the scan during treatment.

Secondary outcome

The secondary endpoint is progressive disease according to Response Evaluation

Criteria in Solid Tumors (RECIST) criteria, after 3 months of treatment.

Progression is defined as the appearance of new disease or an increase of 20%

in the sum of the longest diameters of the target lesions.

Study description

Background summary

The majority of renal cell carcinomas (RCC) is characterized by profound angiogenesis because of inactivation of the Von Hippel Lindau gene. Angiogenesis inhibitors are established first line treatment options in the metastatic setting. Patients with progressive disease during or after treatment with angiogenesis inhibitors can benefit from treatment with everolimus, an oral mTOR inhibitor that resulted in doubling of progression free survival in a phase III study. Currently it is not possible to predict which patient will benefit from treatment with mTOR inhibitors. A predictive biomarker for efficacy of mTOR inhibitors is urgently needed as it may spare the patients unnecessary side effects, safes costs for the society as mTOR inhibitors are are very expensive agents, and may speed up research on new drugs, drug combinations and drug dosing. One of the actions of mTOR inhibitors is blockage

of production of vascular endothelial growth factor (VEGF), and this is thought to be the primary mechanism that is responsible for antitumor activity in RCC. We hypothesize that non-invasive measurement of VEGF in the tumour and its surroundings by 89Zr-bevacizumab PET imaging before and shortly after start of everolimus is a good readout of efficacy of everolimus in patients with RCC.

Study objective

The primary objective of the study is to evaluate the feasibility of 89Zr-bevacizumab PET imaging as a biomarker before and during treatment with everolimus in patients with metastatic RCC. 89Zr-bevacizumab PET imaging will be regarded a promising biomarker if uptake changes after institution of treatment.

Study design

This is a pilot study for evaluation of 89Zr-bevacizumab PET imaging as a biomarker during treatment with everolimus in patients with mRCC. 89Zr-bevacizumab PET imaging will be performed before start of treatment and after 2 and 6 weeks of treatment .

Study burden and risks

Patients will be intravenously injected at 3 time points with 37MBq, this results in a cumulative radiation dose of 54 mSv . Some patients will have their scans with a PET/CT camera, this results in an additional radiation dose of 1.5 mSv per scan (total dose 58.5 mSv).
According to ICRP 62 this radiation dose falls in category III (moderate risk). Life expectancy of the patients is limited because of their incurable renal cell carcinoma, making the risk of development of a secondary malignancy clinically likely not relevant.
Patients have to pay 3 extra visits to the hospital for tracer injection. PET scans will be performed on regular visit days. Blood samples for biomarkers will be drawn during routine blood investigations.
There is no direct benefit for the patients in this study. If 89Zr-bevacizumab PET imaging however is a predictive biomarker for angiogenesis inhibitors, many patients can be spared unnecessary side effects and society can be spared costs of futile treatment in the future.

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

•metastatic renal cell cancer with
•Intention to start treatment with everolimus
•WHO performance score <= 2
•measurable disease with x-ray or CT scan, at least one site of disease must be unidimensionally measurable as follows:
X-ray > 20 mm
Spiral CT scan > 10 mm
Non-spiral CT scan > 20 mm
•>= 18 years
•not pregnant or nursing
•women of childbearing potential must use effective contraception
•absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial
•before patient randomization, written informed consent must be given according to GCP, and local regulations

Exclusion criteria

Are formulated as "no existence of"in inclusion criteria

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):	15-01-2010
Enrollment:	14
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	89Zr-bevacizumab
Generic name:	89Zr-bevacizumab

Ethics review

Approved WMO Date:	24-09-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-10-2009
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-12-2011
Application type:	Amendment
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
EudraCT	EUCTR2009-014257-32-NL
ClinicalTrials.gov	NCT01028638
CCMO	NL28799.042.09