Zirconium-89-girentuximab PET/CT imaging in patients suspected of primary or relapse clear cell renal cell carcinoma: The impact on clinical decision making

Published: 14-10-2015
Last updated: 19-04-2024

Objective: To assess the impact of zirconium-89-girentuximab PET/CT on clinical decision making in patients suspected of primary, recurrent or metastatic clear cell renal cell carcinoma.

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

Summary

ID

NL-OMON42374

Source
ToetsingOnline

Brief title
Zirconium-89-girentuximab PET/CT imaging in renal cell carcinoma

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
renal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Girentuximab, PET/CT, Renal cell carcinoma

Outcome measures

Primary outcome

Impact on clinical decision making, defined as present or absent:

* Absent: e.g. no change in treatment or follow-up

* Present: e.g. change in follow-up schedule, change in surgical technique, be more certain of your treatment strategy, change from surgery to active surveillance, or change from surgery to systemic treatment.

Secondary outcome

The amount of biopsies or surgery that are prevented by zirconium-89-girentuximab PET/CT.

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Study description

Background summary

Conventional imaging studies cannot reliably distinguish benign solid lesions from renal cell carcinoma (RCC) [1-4]. So, more advanced imaging methods are needed, to prevent invasive biopsies or unnecessary surgeries. Similarly, for unambiguous detection of lesions suspect for metastatic and relapse RCC during follow-up imaging methods need to be improved. Currently, SPECT/CT imaging using Indium-111-labeled girentuximab is used for this purpose. Girentuximab is an antibody that recognizes Carbonic Anhydrase IX (CAIX) on the cell surface of clear cell renal cell carcinomas (ccRCC). The high sensitivity and specificity of radiolabeled girentuximab to detect ccRCC have been confirmed in multiple studies [5-7]. Thus, radiolabeled girentuximab is used as a valuable and noninvasive tool in clinical decision making. Combining the superior characteristics of PET (high resolution) with the use of the residualizing

radionuclide Zirconium-89 are major steps forward in the development of this imaging biomarker. Although the accuracy of radiolabeled girentuximab has been studied extensively, the impact on clinical decision making has not been studied before. For implementation of radiolabeled girentuximab into clinical practice, the scan should have impact on clinical decision making. Our hypothesis is that zirconium-89-PET/CT imaging has an important impact on clinical decision making in patients suspected of primary, recurrent or metastatic renal cancer in whom conventional diagnostics are inconclusive.

Study objective

Objective: To assess the impact of zirconium-89-girentuximab PET/CT on clinical decision making in patients suspected of primary, recurrent or metastatic clear cell renal cell carcinoma.

Study design

Study design: This is a single center, single arm and open label study.

Thirty patients will be included in whom conventional diagnostics are inconclusive. During a multidisciplinary team (MDT) the hypothetical next step in the clinical process will be noted (e.g. further diagnostics, treatment or active surveillance). Subsequently, in these patients a Zirconium-89-girentuximab PET/CT will be acquired. Patients will receive a single intravenous dose of 5 mg Zirconium-89-girentuximab (37 MBq). A PET/CT scan will be acquired 4 or 5 days after injection. The Zirconium-89-girentuximab PET/CT will be interpreted by a clinician with extensive experience in radiolabeled girentuximab imaging. The results of the PET/CT will be discussed during the MDT and will be used to decide what the next step in the clinical process will be. This step will be compared with the hypothetical next step from the MDT before the scan. For the individual patient will be recorded whether or not the PET/CT scan had impact on clinical decision making. Independently of the result of PET/CT imaging patients will remain under close follow-up (standard of care). After one year of follow-up an post-hoc analysis will be performed to evaluate the clinical decision based on the PET/CT. For this purpose data of follow-up imaging and histological data will be used.

Intervention

Administration of 5 mg/37 MBq zirconium-89-girentuximab followed by PET/CT after 4 days.

Study burden and risks

The burden of study participation is low, since it only consists of a tracer

injection and a PET/CT. The risks associated with the antibody injection are low. Worldwide girentuximab has been administered intravenously to more than 2,500 patients and adverse reactions have never been observed. The mean effective dose after administration of a Zirconium-89-labeled monoclonal antibody is 0.6 mSv/MBq [8]. Effective radiation dose of 37 MBq 89Zr*labeled girentuximab will be approximately 22 mSv. Considering the patient category (majority older than 50 years and/or metastatic disease) the relative dose will be 22/5 = 4.4 mSv which is an acceptable dose according to the ICRP 62 [9]. Furthermore, study participation may give direct benefit to the individual patient, because it might prevent an unnecessary biopsy or surgical procedure. The risk associated with a false-negative PET/CT is low, since lesions that cannot be visualized with PET, i.e. do not express CAIX, are mostly benign or low grade tumors, like chromophobic RCC. Furthermore the window of opportunity to treat patients with RCC is wide and patients will remain under close follow-up. Therefore this study is justified.

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

His or her clinician should face a diagnostic dilemma;
- patients with a renal mass of unknown origin, or
- patients with a primary renal mass in whom it is unclear whether there is metastatic disease, or
- patients with a history of clear cell RCC with a suspicion of relapse or metastatic disease.
*
Age over 18 years;Signed informed consent

Exclusion criteria

History of a CAIX-negative or non clear cell RCC.
Administration of tyrosine kinase inhibiters within 1 month prior to inclusion.
Known hypersensitivity or HACA against Girentuximab.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-12-2015
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	14-10-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-08-2018
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	NL54190.091.15

Study results

Date completed:	06-06-2017
Actual enrolment:	30

Summary results
Trial is onging in other countries