Follow up after percutaneous MR-guided cryoablation of Small Renal Masses.

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The primary objective is to evaluate the feasibility of early therapeutic effect evaluation by performing early follow up imaging after percutaneous MR-guided cryoablation of pT1a renal cell carcinoma. Secondary objective is to assess the outcomes...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational invasive

Summary

ID

NL-OMON40801

Source
ToetsingOnline

Brief title
FU after cryoablation of small renal masses (SRM).

Condition

- Renal disorders (excl nephropathies)

Synonym
kidney cancer, Renal cell carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: European Union

Intervention

Keyword: Cryoablation, Follow up, MR guided, Renal cell carcinoma

Outcome measures

Primary outcome

Positive and negative predictive value of MRI and Indium-111-Girentuximab-DOTA

SPECT 4-6 weeks after intervention.

Secondary outcome

Residual and recurrent free survival at 3 months follow up.

Study description

Background summary

About 2-3% of newly diagnosed cancer concerns renal cell carcinoma (RCC). Approximately 90% of all renal malignancies is accounted for by RCC, of which approximately 80% consists of clear cell RCC. Over the last years the number of incidentally diagnosed RCCs has been growing due to more frequent use of abdominal imaging. Due to this the number of smaller and lower staged RCCs has been growing over the last years.

Cryoablation
Currently most small renal tumors (masses <=7 cm) are treated by nephron sparing surgery. However, partial nephrectomy better preserves renal function compared to radical nephrectomy, possible disadvantage of this surgical approach remains unintended damage of healthy kidney parenchyma due to a intraprocedural warm ischemic time interval of the entire kidney. Also, surgery comes with significant morbidity and might be unsuitable in case of previously performed surgery, multiple tumors in an ipsilateral kidney or unsuitability for general anesthesia due to the extent of co morbidities. Therefore, widespread interest in more minimal invasive therapies, especially thermal ablative therapies, has arisen the last couple of years. Studies regarding the effect of cryoablation on tumor tissue have been studied before and showed the desired results. Clinical studies proved cryoablation to be a safe treatment modality with low risk of complications and promising results. Also the preservation of kidney function seemed effective using cryoablation.

Intraprocedural imaging

In order to minimize the invasive character and thereby reducing post interventional morbidity, cryoablation is currently mostly performed percutaneously. Most challenging in case of percutaneous approach is to avoid residual vital tumour tissue by adequately ablating the entire volume of the tumour. Therefore, intraprocedural imaging is of utmost importance. The advantage of CT imaging is good real time visualisation during the procedure, however the patient will be explored to ionising radiation. MR imaging has all the advantages of CT imaging, but enables monitoring without the need for ionising radiation. Also differentiation between ice ball formation and other surrounding anatomical structures are better visualised using MR imaging. Due to its advantages MR imaging is the preferred imaging modality used in our clinic. The reported technical success and complication rates using percutaneous approach are excellent, regardless of imaging modality used.

Follow up imaging

Consensus on follow up imaging after percutaneous cryoablation is lacking. Current guidelines state that the objective of follow up imaging should be proper therapy effect evaluation and early and asymptomatic detection of recurrent disease (local recurrence or distant metastasis). However, no consensus is reached on the preferred imaging algorithm, mostly due to a lack of prospective clinical studies validating imaging schedules or other high quality evidence. Therefore current guidelines on follow up imaging are mostly based on prognostic nomograms. The lack of consensus results in different available guidelines that are equivocal and leave many decisions to the discretion of the treating urologist. EAU guidelines propose first post-procedural imaging at 6 months follow up, however, it is stated that a stricter schedule may be required after cryoablation. In contrast AUA guidelines are stricter and propose follow up imaging at 3 and 6 months following cryoablation. In our clinic first post procedural imaging is performed at 3 months follow up. In contrast, many radiologists recommend earlier first imaging after ablation in order to detect residual tumour in an early stage. Criteria for suspicion of residual disease on follow up imaging are established and widely used, however interpretation of early performed imaging may still be challenging due to post procedural peripheral rim enhancement and increase in volume of the ablated region both not necessarily indicating residual disease. Therefore biopsy should be performed to confirm these early imaging findings.

Girentuximab

Previously the potential role of Fluorine-18-Deoxyglucose Positron Emission Tomography (FDG-PET) in evaluating therapy efficacy after thermal ablation of hepatic metastases has been studied. Interestingly FDG-PET revealed recurrences earlier than conventional imaging techniques used. However FDG-PET has not proven to have an additional value in diagnosis of RCC. More promising result are seen in RCC using Single Photon Emission Computed Tomography (SPECT). Carbonic Anhydrase IX (CAIX) is a cell surface antigen in renal cancer that is highly and homogenously expressed in >95% of clear cell renal cell carcinoma

(ccRCC). Girentuximab (chimeric monoclonal antibody a.k.a. G250 or cG250) has a high affinity for the CAIX antigen. Due to the specific targeting of Girentuximab for ccRCC and the excellent options to visualize target lesions , especially when labelled with Indium-111, Girentuximab is already in use as a diagnostic tool in case of renal masses for differentiation between benign and malignant tumours. Also it has been proven efficient in determining new metastatic sites. Because of the expression pattern, a positive lesion on Indium-111-Girentuximab SPECT is always considered a malignant neoplasm of the kidney, most likely ccRCC or a distant metastasis of that.

Study objective

The primary objective is to evaluate the feasibility of early therapeutic effect evaluation by performing early follow up imaging after percutaneous MR-guided cryoablation of pT1a renal cell carcinoma. Secondary objective is to assess the outcomes of the performed percutaneous MR-guided cryoablation procedures of pT1a renal cell carcinoma at 3 months follow up.

Study design

After inclusion patients will undergo a pre procedural Indium-111-Girentuximab SPECT scan (additional) after which a MR guided cryoablation is performed (normal clinical practice). In case of proven targetting on the pre procedural Indium-111-Girentuximab SPECT scan a second Indium-111- Girentuximab SPECT will be performed 4-6 weeks after the treatment (additional). At the same time the latter Indium-111-Girentuximab SPECT is performed a postprocedural MRI will be performed (additional). Next imaging will be performed at 3 months post procedural using MRI (normal clinical practice) after which a biopsy will be taken from the ablative lesion to confrim imaging findings(additional).

Study burden and risks

Since the additional MRI and Indium-111-Girentuximab-DOTA SPECT are experimental, the decision for eventual additional treatment due to residual or recurrent disease will be made based on the follow up MR imaging and performed biopsy at 3 months. In this matter, no individual benefit is established for these patients. Individuals may benefit from the pre procedural Indium-111-Girentuximab-DOTA SPECT as an additional diagnostic tool as for histological exam of the taken biopsy sometimes is not representive. A positive lesion is always considered a malignancy of the kidney, most likely a ccRCC. Also the additional biopsy may reveal residual tumor after a false negative MRI scan at 3 months follow up. In that case additional treatment will be considered.
Potential risks are complications of MRI (burden of heating and noise, risks of contrast reactions against gadolinium) and patient burden in form of time investment and physical discomfort during biopsy and inserting an infusion

needle before imaging. No allergic reactions to Girentuximab have been observed during clinical trials. The Indium-111-Girentuximab-DOTA SPECT comes with minimal exposure to additional radiation (intravenous injection of 100 MBq Indium-111-Girentuximab-DOTA and a low dose CT scan during SPECT CT scanning results in an approximate effective dose of 8.3 mSv). Biopsy is associated with low morbidity and with the current techniques used the risk of seeding is negligible. The risk of the additional biopsy consists of spontaneously resolving subcapsular/perinephric hematoma and hematuria. More severe bleeding is rare (0-1.4%) and generally self limiting.

The only applicable group for undergoing experimental imaging after cryoablation is the group that actually underwent renal tumor cryoablation, therefore we select these patients for this study.

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

>50 years of age;
At least one untreated T1a tumour of one kidney (tumour <= 4 cm in greatest dimension);
Signed IRB-approved informed consent form.

Exclusion criteria

Relative contra indications for MR imaging (metal device/foreign bodies, claustrophobia);
Pregnancy or breast feeding;
Known hypersensitivity or HACA against Girentuximab.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-02-2015
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Magnetic Resonance Imaging
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	04-08-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-12-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-12-2015
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	NL48292.091.14