Ablative tReatment of inoperable REnal cell carcinoma using STereotactic body Radiotherapy

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To evaluate safety and feasibility of stereotactic body radiation therapy (SBRT) with fiducial markers in inoperable patients with renal cell carcinoma (RCC).The treatment is considered successful if all 5 treatments are completed and if in total

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

Summary

ID

NL-OMON46152

Source
ToetsingOnline

Brief title
ARREST

Condition

- Renal and urinary tract neoplasms malignant and unspecified
- Renal disorders (excl nephropathies)
- Renal and urinary tract therapeutic procedures

Synonym
kidney cancer, Renal cell carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

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

Intervention

Keyword: Inoperable, Kidney, Renal cell carcinoma, SBRT

Outcome measures

Primary outcome

Newly developed acute toxicity grade 3 or more according to the Common

Terminology Criteria for Adverse Events (CTC-AE) version 4.0.

The treatment is considered successful if all 5 treatments are completed and if

in total <15% of the patients (=5 patients) report a toxicity * grade 3.

Secondary outcome

Secondary endpoints will be treatment response, (late) toxicity assessment,

local control rate and quality of life assessment.

Study description

Background summary

The incidence of renal cell carcinoma (RCC) is increasing due to the increased use of diagnostic imaging. 60-70% of the RCC are incidentaloma*s, often classified as small renal masses (SRM). The standard treatment of RCC is (partial-) nephrectomy. Alternatives to this treatment are less invasive techniques like radio frequency ablation (RFA) and cryoablation (CA). So far, only these invasive treatments of RCC has been shown to be curative. An alternative curative treatment option (completely non-invasive or with the use of fiducial markers) is stereotactic body radiation therapy (SBRT), which has shown promising results in Toronto the last years.
In this study, we aim to evaluate the safety and feasibility of SBRT for patients with inoperable RCC on a conventional cone beam computed tomography (CBCT) linear accelerator.

Study objective

To evaluate safety and feasibility of stereotactic body radiation therapy

(SBRT) with fiducial markers in inoperable patients with renal cell carcinoma (RCC).
The treatment is considered successful if all 5 treatments are completed and if in total <15% of the patients (=5 patients) report a toxicity * grade 3.

Study design

Single arm prospective study.

Intervention

Prior to treatment, patients will undergo fiducial marker placement (in combination with a biopsy, if RCC has not been pathology proven), followed by a contrast enhanced planning computed tomography (CT)-scan and a contrast enhanced MRI-scan. Fiducial markers will be used as this increases visibility of the tumor and therefore the accuracy of radiotherapy, particularly the irradiated healthy kidney tissue will be diminished by using this approach. Baseline toxicity and quality of life will be assessed.
Radiotherapy will be delivered in five fractions of 7 Gy every other day. After treatment, follow-up will be at 1, 3, 6 and 12 months at the Radiotherapy department, followed by standard follow-up by the urologist. An additional contrast enhanced MRI scan will be performed after the 2nd treatment fraction, and after 6 (+/- 14 days) and 12 (+/- 14 days) months to assess treatment response. Toxicity and quality of life will be assessed during follow-up.

Study burden and risks

The treatment in this study will be the same as the standard SBRT treatment currently used at Sunnybrook Hospital (Odette Cancer Centre in Toronto) for patients with inoperable RCC, except for the planning MRI, the MRI after the 2nd radiotherapy fraction and after 6 months (+/- 14 days) and 12 months (+/- 14 days). The same dose fractionation scheme and dose constraints for the healthy tissues will be used. In addition, placement of fiducial markers will take place to target the tumor prior to each treatment fraction. Quality of life and toxicity will be assessed until 12 months after treatment, followed by standard follow-up by the urologist.
A potential benefit of this study is that it allows for a curative intent treatment for patients with inoperable RCC in a population with otherwise no perspective on a curative treatment.
We don*t think severe (grade 3 or higher) toxicity resulting from SBRT treatment will occur in most patients (when adhering to the healthy tissue dose constraints) based on previous (although with limited follow-up) SBRT study results. The placement of fiducial markers (and if not previously performed also the biopsy), may potentially cause infection and bleeding.
Moreover, this study is a required step in the development of MRI-guided

radiotherapy for operable and inoperable patients 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

- Inoperability, or when a patient refuses surgery (i.e. not eligible for (partial-) nephrectomy or RFA);
- Kidney function allows for intervention, as evaluated by treating urologist (taking into account eGFR and renogram);
- Age * 18 years;
- Written informed consent;
- Diagnosis of RCC confirmed by pathology (in case determined after informed consent, patients who are not eligible anymore (no RCC) will be excluded).

Exclusion criteria

- Evidence of metastatic disease;
- Exclusion criteria for contrast enhanced MRI scan, according to the protocol of the department of Radiology, UMC Utrecht;
- Patients with one functioning kidney;
- Prior renal surgery (partial nephrectomy);
- Prior radiotherapy on upper abdomen;
- Unsafe to have fiducial marker implantation: i.e. anticoagulant agents use other than acetylsalicyl acid, which cannot be safely stopped/bridged for implantation;
- WHO * 3;
- Chemotherapy < 3 weeks before treatment;
- Targeted therapy (sunitinib etc) * 7 days before treatment.

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):	22-09-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	30-03-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	20-12-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
ClinicalTrials.gov	NCT02853162
CCMO	NL55770.041.15