Towards MRI guided radiotherapy of renal cell carcinoma

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To make MRI suitable for an MRI-only workflow for magnetic resonance (MR)-guided (MRlinac) stereotactic radiotherapy for localized RCC. The objective of the current study will be MRI-sequence optimisation. Sequences will be optimized for MR-based...

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-OMON42445

Source ToetsingOnline

Brief title MRI-RCC

Condition

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

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: Kidney, MRI, Radiotherapy, Visualization

Outcome measures

Primary outcome

To make MRI suitable for MR-guided (MR-linac) stereotactic radiotherapy for

localized RCC. The current predicate MRI work includes MRI-sequence

optimisation (to allow for MR-based delineation) and MR-guidance during

treatment.

Secondary outcome

Not applicable.

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 frequent ablation (RFA) and cryoablation (CA). So far, only (less-) invasive treatment of RCC has been shown to be curative. An option for a non-invasive curative treatment would be magnetic resonance imaging (MRI)-guided radiotherapy. In this study we want to evaluate technical feasibility of imaging lesions suspect for RCC by MRI. The purpose is to develop and optimize an MRI scanning protocol for radiotherapy, in order to work towards MRI-guided radiotherapy.

Study objective

To make MRI suitable for an MRI-only workflow for magnetic resonance (MR)-guided (MR-linac) stereotactic radiotherapy for localized RCC. The objective of the current study will be MRI-sequence optimisation. Sequences will be optimized for MR-based delineation and MR-guidance during radiotherapy treatment.

Study design

Prospective imaging (MRI) study.

Study burden and risks

Patients will undergo a contrast enhanced MRI scan with gadolinium, which will take less than 45 minutes. The total visit to the department (including patient preparation and changing of clothes) will last approximately 60 minutes. There are no patient specific benefits by participating in this study, however this study is a required step in the development of MRI-guided ablative radiotherapy for operable and inoperable RCC 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)

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Inclusion criteria

- Patients with a solid lesion suspect for RCC or a cystic lesion Bosniak classification > IIF;
- * 18 years;
- Written informed consent.

Exclusion criteria

- Fulfilling one of the exclusion criteria for MRI at 1.5T/3T according to the protocol of the department of Radiology, UMC Utrecht;

Fulfilling the exclusion criteria for the Gadovist gadolinium (glomerular filtration rate (GFR) of < 30 mL/min/1.73m2) (see also 'MRI contra indicaties Gadolinium gebruik' - guidelines UMC Utrecht, versie 5; april 2015);

- Patients with a known Gadovist allergy;
- Metastatic (regional or distant) RCC;
- Bosniak classification * IIF.

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):	17-12-2015
Enrollment:	30
Туре:	Actual

Ethics review

Approved WMO

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Date:	05-10-2015
Application type:	First submission
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 CCMO

ID NL53592.041.15