

Validation of the diffusion MRI signal in kidney tumours: a pilot study

Published: 09-04-2015

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The primary objective of this study is to compare diffusion MRI derived parameters with the histological categorization of kidney tumours.

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

Summary

ID

NL-OMON43829

Source

ToetsingOnline

Brief title

Validation of kidney DW-MRI

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym

kidney tumour, Renal Cell Carcinoma

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Twente

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

Intervention

Keyword: Diffusion-MRI, DTI, IVIM, Kidney tumours

Outcome measures

Primary outcome

The main study parameters are diffusion MRI derived parameters: FA, MD, pseudodiffusion coefficients and perfusion fractions, that will be correlated with the histological kidney cancer type (clear cell, chromophobe, cystic and papillary renal cell carcinoma).

Secondary outcome

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Study description

Background summary

The arrangement of the microstructures of the kidneys, particularly tubules and blood vessels, is closely associated with kidney function. With diffusion MRI methods the diffusion of water molecules can be mapped. Water diffusion in renal medullar tissue is restricted by the radial organization of tubules, collecting ducts and vessels, and is therefore greater in the radial direction than in other directions (hence, the diffusion is *anisotropic*). Recent studies showed that anisotropy in the kidney medulla can be measured with diffusion tensor imaging. Moreover, with fiber tractography the radial orientation of the kidney structure can be visualized. Furthermore, intravoxel incoherent motion (IVIM) analysis enables separation of different water motion processes (e.g. perfusion and diffusion) based on differences in these processes.

In a previous study, a comprehensive protocol for diffusion MRI imaging of the kidneys, including DTI and IVIM analysis and visualization using tractography, was developed and tested. The aim of this follow-up pilot study is to compare diffusion MRI derived parameters to the histologically established kidney tumor type. In this study both diffusion methods (DTI and IVIM) will be combined and applied to a renal pathology for the first time, resulting in a broad range of diffusion information. This information will, on the one hand, result in a better understanding of the diffusion signal. On the other hand, it will be the first step towards the use of diffusion MRI methods for in vivo categorization of kidney tumor type.

Study objective

The primary objective of this study is to compare diffusion MRI derived parameters with the histological categorization of kidney tumours.

Study design

Pilot study in 15 patients and 5 healthy volunteers.

Study burden and risks

Volunteers are subjected to a MRI scan of 45 minutes in a 3.0T MRI- scanner (Philips Medical Systems, Best). There are no known risks associated with MRI, beside temporary dizziness and claustrophobia. No contrast is needed. The burden is relatively low.

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

- * Volunteers are healthy
- * Volunteers and subjects are 18 year or older.
- * Volunteers and subjects are capable and prepared to sign an informed consent.
- * Subjects are eligible for radical nephrectomy
- * Subjects are planned to undergo nephrectomy

Exclusion criteria

- * Subjects and volunteers with contra-indications for MRI (like a pacemaker, claustrophobia).
- * Subjects and volunteers with large (known) deviation in kidney anatomy (like horseshoe kidney).
- * Refusal of volunteers and subjects to be informed of chance findings possibly relevant to their health.
- * Subjects and volunteers with kidney pathologies (other than kidney tumor)

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 27-05-2015

Enrollment: 20

Type: Actual

Ethics review

Approved WMO

Date: 09-04-2015

Application type: First submission

Review commission: METC Twente (Enschede)

Approved WMO

Date: 06-09-2016

Application type: Amendment

Review commission: METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24559

Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL52411.044.15
OMON	NL-OMON24559