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

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON24559

**Source**
Nationaal Trial Register

**Brief title**
Validation of kidney DW-MRI

**Health condition**

kidney, kindey tumor, renal cell carcinoma

### Sponsors and support

**Primary sponsor:** University of Twente
**Source(s) of monetary or material Support:** University of Twente

### Intervention

### Outcome measures

**Primary outcome**

De primaire onderzoeksvariabelen zijn de diffusie-MRI verkregen parameters: FA, MD, pseudodiffusie coefficienten en perfusie fracties. Deze worden gecorreleerd aan de histologisch vastgestelde tumor type (clear cell, chromophobe, cystic en papillary renal cell carcinoma).

### Secondary outcome

N/A

## 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 de 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 design

N/A

### Intervention

Diffusion MRI scan, including diffusion-tensor imaging (DTI), intra-voxel incoherent motion (IVIM) and tractography

## Contacts

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# Eligibility criteria

## 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 |
| Intervention model: | Other |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 27-05-2015 |
| Enrollment: | 21 |
| Type: | Anticipated |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 18-03-2015 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 43829
Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL4859 |
| NTR-old | NTR5104 |
| CCMO | NL52411.044.15 |
| OMON | NL-OMON43829 |

# Study results