

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

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|                             |                                                     |
|-----------------------------|-----------------------------------------------------|
| <b>Ethische beoordeling</b> | Positief advies                                     |
| <b>Status</b>               | Werving nog niet gestart                            |
| <b>Type aandoening</b>      | -                                                   |
| <b>Onderzoekstype</b>       | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON24559

### Bron

Nationaal Trial Register

### Verkorte titel

Validation of kidney DW-MRI

### Aandoening

kidney, kindey tumor, renal cell carcinoma

## Ondersteuning

**Primaire sponsor:** University of Twente

**Overige ondersteuning:** University of Twente

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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

# Toelichting onderzoek

## Achtergrond van het onderzoek

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.

## Onderzoeksopzet

N/A

## Onderzoeksproduct en/of interventie

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

# Contactpersonen

## Publiek

Postbus 217

S. van Baalen

Enschede 7500 AE  
The Netherlands  
+31 53 489 5596

## **Wetenschappelijk**

Postbus 217

S. van Baalen

Enschede 7500 AE  
The Netherlands  
+31 53 489 5596

## **Deelname eisen**

### **Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)**

- \* 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

### **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

- 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)

## Onderzoeksopzet

### Opzet

|                  |                                                     |
|------------------|-----------------------------------------------------|
| Type:            | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders                                              |
| Toewijzing:      | N.v.t. / één studie arm                             |
| Blinding:        | Open / niet geblindeerd                             |
| Controle:        | N.v.t. / onbekend                                   |

### Deelname

|                         |                          |
|-------------------------|--------------------------|
| Nederland               |                          |
| Status:                 | Werving nog niet gestart |
| (Verwachte) startdatum: | 27-05-2015               |
| Aantal proefpersonen:   | 21                       |
| Type:                   | Verwachte startdatum     |

## Ethische beoordeling

|                 |                  |
|-----------------|------------------|
| Positief advies |                  |
| Datum:          | 18-03-2015       |
| Soort:          | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43829  
Bron: ToetsingOnline  
Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

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

## Resultaten