

# Optimization of MR diffusion image quality and the use of low-b-values at intravoxel incoherent motion in head and neck

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Primary objective: - Optimization of MR diffusion quality in head and neck squamous cell carcinoma by an extension of the scan protocol and a pillow filled with pineapple juice.

Secondary objective:- To determine the most optimal amount and...

**Ethical review**

Approved WMO

**Status**

Recruitment stopped

**Health condition type**

Miscellaneous and site unspecified neoplasms benign

**Study type**

Observational non invasive

## Summary

### ID

NL-OMON45342

**Source**

ToetsingOnline

**Brief title**

DWI optimization

### Condition

- Miscellaneous and site unspecified neoplasms benign

**Synonym**

Head & Neck cancer, squamous cell carcinoma head and neck

**Research involving**

Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

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

## Intervention

**Keyword:** Diffusion, Intravoxel Incoherent motion, Magnetic Resonance imaging

## Outcome measures

### Primary outcome

Quality Diffusion-weighted images

Diffusion parameters (ADC), IVIM-parameters (D, D\*, f)

Reproducibility IVIM parameters

### Secondary outcome

Optimale aantal en distributie van b-waardencombinatie

## Study description

### Background summary

Nowadays more imaging techniques are used for diagnostic purposes, treatment planning, non-invasive treatment monitoring of (chemo)radiotherapy or for outcome prediction. Continuous optimization of this imaging is necessary to optimize the sensitivity and specificity for both diagnosis and prognosis.

On one hand, conventional MRI images are specifically directed to the anatomy of (tumor) tissue. On the other hand, perfusion MRI (contrast enhancement) and diffusion MRI can map physiology in tissue, which can be of value in determining precise staging and predictive response rate. In addition, there are indications that changes in functional parameters occur faster than the classic response parameters based on size (diameter or volume change). Intravoxel incoherent motion (IVIM) is a technique within the diffusion-weighted MRI that has recently emerged strongly. This image technique contribute to the characterization of a tumor, for example to what extent microperfusion and diffusion is present in tissue or tumor. This study will be investigated because IVIM parameters vary between tissues in head and neck and

this is not previously described in literature, especially for low B values\*. The main problem of imaging in the head-neck area is the inhomogeneity of the magnetic field. This is expected to be greatly improved by draining a fluid-filled pillow around the neck, so that there are fewer air-tissue transitions near the neck region. This fluid contains manganese (pineapple) juice to reduce T2 time, so that the liquid does not give an excessively strong signal that can complicate the assessment of the MRI images of the neck.

## **Study objective**

Primary objective:

- Optimization of MR diffusion quality in head and neck squamous cell carcinoma by an extension of the scan protocol and a pillow filled with pineapple juice.

Secondary objective:

- To determine the most optimal amount and distribution of b-values to obtain a good bi-exponential fit with IVIM.
- To determine IVIM-parameters of normal tissue of different areas/structures in head and neck
- To test the reproducibility of IVIM parameters in healthy head and neck tissue.

## **Study design**

Observational

## **Study burden and risks**

Patients have to lie still for about 6 minutes after the normal MRI, without risks or benefits.

## **Contacts**

### **Public**

Vrije Universiteit Medisch Centrum

De Boelelaan 1117  
Amsterdam 1081 HV  
NL

### **Scientific**

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De Boelelaan 1117  
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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Healthy volunteer
- o No surgical/oncological history in head & neck region;- Patient with head and neck cancer
- o Bulky T2, T3, T4 squamous cell carcinoma;- Acquired written informed consent

### Exclusion criteria

- Contraindications MRI
- Pregnancy

## Study design

### Design

|                     |                                 |
|---------------------|---------------------------------|
| Study type:         | Observational non invasive      |
| Intervention model: | Other                           |
| Allocation:         | Non-randomized controlled trial |
| Masking:            | Open (masking not used)         |
| Control:            | Active                          |
| Primary purpose:    | Diagnostic                      |

## Recruitment

|                           |                     |
|---------------------------|---------------------|
| NL                        |                     |
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 20-07-2017          |
| Enrollment:               | 30                  |
| Type:                     | Actual              |

## Ethics review

|                    |                    |
|--------------------|--------------------|
| Approved WMO       |                    |
| Date:              | 17-05-2017         |
| Application type:  | First submission   |
| Review commission: | METC Amsterdam UMC |

## 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             |
|----------|----------------|
| CCMO     | NL59736.029.16 |

## Study results

|                   |            |
|-------------------|------------|
| Date completed:   | 01-06-2019 |
| Actual enrolment: | 10         |