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. Secundary 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, treatmentplanning, 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 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 becaus 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.

Secundary 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 healty heak and neck tissue.

Study design

Observational

Study burden and risks

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

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

- 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