MRI-guided identification of response to (chemo)radiotherapy in patients with head and neck cancer

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24896

Source
NTR

Brief title
PREDICT

Health condition

Head and Neck Squamous Cell Carcinoma (HNSCC)
Oropharyngeal cancer
Cancer of the oral cavity
Hypopharyngeal cancer
Laryngeal cancer
Hoofd-hals kanker

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: University Medical Center Utrecht

Intervention

Outcome measures

Primary outcome

The primary endpoint is the predictive value of DW-MRI after the start of radiotherapy based on a single scan during treatment.

Secondary outcome

- ADC level and tumor volume pretreatment

- Change ADC level and gross tumor volume during therapy

- The optimal time point for MRI scanning during treatment in order to predict treatment outcome

Study description

Background summary

-

Study objective

The change in 'apparent diffusion coefficient' (ADC), obtained using diffusion weighted MRI, from pre-treatment to intra-treatment is lower in HNSCC patients with a poor response to (chemo)radiotherapy than in HNSCC patients with a good response to (chemo)radiotherapy.

Study design

Four additional MRI scans will be made in week 2, 3, 4 and 5 of the radiotherapy treatment. After finishing treatment study participants will receive 2 years of follow up as per standard post-treatment HNSCC protocol.

Intervention

Patients meeting the inclusion criteria will be recruited from the department of head and neck surgical oncology. Pretreatment imaging consist of standard head and neck MRI sequences and added diffusion weighted sequence. Subsequently all patients will receive radiotherapy with or without concomitant chemotherapy following standard procedure. During the radiotherapy course additional MRI imaging including diffusion weighted sequences will be acquired in the study group. The scans will be planned for week 2, 3, 4 and 5 of the radiotherapy course.

Contacts

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Eligibility criteria

Inclusion criteria

- Squamous cell carcinoma

- T2, T3 or T4 Oral cavity or pharynx

- T3 or T4 larynx

- Technically resectable

- Scheduled for primary (chemo)radiation with curative intent

- ‘Informed consent’ signed by patient

Exclusion criteria

- Age < 18 years

- Pregnancy

- Patients unsuited for MRI examination as defined in the protocols of the Radiology department.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2016
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	25-11-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 56355
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5955
NTR-old	NTR6136
CCMO	NL57164.041.16
OMON	NL-OMON56355

Study results