Predictive value of Diffusion weighted MRI in patients with HNSCC treated by (chemo)radiotherapy (PREDICT study)

Published: 03-08-2016
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To determine the prognostic value of diffusion-weighted MRI and circulating tumor DNA (ctDNA) performed pre-treatment and during treatment in predicting the locoregional response to (chemo)radiation for HNSCC.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON56355

Source
ToetsingOnline

Brief title
PREDICT

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified
- Upper respiratory tract disorders (excl infections)

Synonym
head and neck squamous cell carcinoma; throat cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

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

Intervention

Keyword: Circulating tumor DNA, DW-MRI, HNSCC, Predictive value

Outcome measures

Primary outcome

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

Secondary outcome

ADC level and tumor volume pretreatment;

Change in ADC levels, ctDNA and gross tumor volume prior to, during and after therapy;

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

Study description

Background summary

The last decade, radiotherapy with or without chemotherapy has become an organ spearing treatment modality for functionally irresectable head and neck squamous cell carcinoma (HNSCC) to retain the best quality of life. The early identification of non-responders to (chemo)radiation would spare a substantial number of patients from the morbidity and the complications of salvage surgery and in such cases may lead to overall improvements in survival if radiotherapy is used, when indicated, as a post-operative modality

Study objective

To determine the prognostic value of diffusion-weighted MRI and circulating tumor DNA (ctDNA) performed pre-treatment and during treatment in predicting the locoregional response to (chemo)radiation for HNSCC.

Study design

This study is a observational study of a prospective cohort containing 100 - 120 consecutive patients, dependent on the amount of patients eligible for both MRI and tumor DNA quantification.

Study burden and risks

In standard clinical practice these patients will undergo pretreatment MRI including a diffusion weighted sequence. In this protocol, included patients will undergo 4 additional MRI exams during treatment. The additional scans will be made on the MRI-scanner at the Department of Radiotherapy. Additional scanning time for the four MRI*s amounts to 20 minutes per exam. If patients provide consent blood and saliva samples will be obtained pretreatment and 4 times during treatment and 1-2 times after treatment in order to examine circulating tumor DNA. The patients have no benefit of the extra MRI sequencesprocedures, as these scans are not used for clinical practice and treatment related decisions. In the future patients may benefit from DW-MRI and circulating tumor DNA quantification during treatment in stopping futile - low chance to cure - (chemo)radiation and switch to surgical treatment with still adjuvant radiotherapy available. This study poses no additional risk to participating patients as DW-MRI is a conventional techniqueconventional techniques with inherent low risk are used.

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

-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 invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	29-12-2016
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	03-08-2016
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	17-05-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	19-07-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-08-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-09-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24896
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL57164.041.16
OMON	NL-OMON24896