The value of combined Quantitative MRI for Treatment Response Assessment in head and neck cancer patients receiving (Chemo)radiotherapy.

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We will measure correlations between serially measured MRI parameters (pretreatment and early during treatment) and therapy outcome (response, locoregional recurrence and overall survival) in patients with HNSCC undergoing chemoradiation (CRT)...

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON56710

Source
ToetsingOnline

Brief title
QTRAC

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
head and neck cancer, squamous cell carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC

Source(s) of monetary or material Support: NWO

Intervention

Keyword: Head and neck, Quantitative Imaging, Squamous cell carcinoma

Outcome measures

Primary outcome

To assess the univariate prognostic value of potential pre- and intratreatment (2-3 weeks after start of CRT) quantitative functional MRI parameters (D, Ktrans or T2*) as candidate biomarkers to predict loco-regional failure in patients with head and neck squamous cell carcinoma within 2 years after treatment.

Secondary outcome

I. To assess the univariate predictive of pre- and intratreatment (2-3 weeks after start of CRT) quantitative functional MRI parameters (D, Ktrans or T2*) to predict distant metastasis and overall survival in patients with head and neck squamous cell carcinoma within 2 years after treatment. II. To assess the effect of CRT on the functional biomarkers after 2-3 weeks of treatment initiation. III. To compare in-house state-of-the-art processing software to CE-labelled analysis pipeline. IV. To assess the correlation of MRI parameters and liquid biopsy findings to test whether both techniques are complementary to each other.

Study description

Background summary

Head and neck squamous cell carcinoma (HNSCC) is the 6th most common malignancy worldwide, with 890,000 patients diagnosed and 450,000 patients dying from this disease each year. For locally advanced diseases, multimodality treatment (e.g. CRT) is required. Still, the 5-year survival rate lags at 40-60% with around half of patients experiencing disease recurrence within the first two years. Currently, patients with advanced stage are typically treated with a standard pre-defined population-based CRT regime, typically administered during seven weeks. CRT targets the tumorous tissue but also inflicts damage to healthy tissue. Treatment response varies among patients, in which some have good responses and might benefit from a reduction of doses to avoid unnecessary toxicity due to overtreatment. Others are confronted with an incomplete response, who possibly benefit from intensification of treatment or switch to salvage surgery. Predictive biomarkers, based on the tumor biological phenotype, can determine the tumour's response to CRT early on in this treatment, and might enable individualization of therapy regimen based on tumour response. This would lead to a more effective and personalized treatment with fewer side effects.
Quantitative MRI has great potential as a predictive biomarker for response assessment as it allows accessing local tissue microstructural properties, probing cell density (IVIM-DWI), tissue perfusion (DCE & IVIM-DWI) and hypoxia (T2*-relaxometry). lt was shown that baseline values of these parameters correlate to overall survival and that changes early in the treatment can be a biomarker for predicting locoregional recurrence free survival.
In this research, we will investigate a combination of quantitative MRI to identify potential biomarkers tor predicting response to (chemo)radiotherapy early on in the treatment.

Study objective

We will measure correlations between serially measured MRI parameters (pretreatment and early during treatment) and therapy outcome (response, locoregional recurrence and overall survival) in patients with HNSCC undergoing chemoradiation (CRT) treatment, which will ultimately enable tailoring treatment to be more patient-specific.

Study design

This is a single-center prospective study. In total 30 head and neck cancer patients receiving standard-of-care CRT will be included who will undergo pretreatment quantitative MRI, and intratreatment (2-3 weeks after treatment initiation) quantitative MRI. Hence, we will obtain IVIM-DWI, DCE, T2*-relaxometry at baseline and 2-3 weeks after the start of CRT in 30 HNSCC patients treated with curative CRT.
MRI will be obtained at Amsterdam UMC (location VUmc) using a 3T MRI scanner. MRI analysis will be done two-fold, once with our state of-the-art in-house machine-learning-based pipeline, and once using CE labelled software (OLEA,

Canon Medical). As a standard of care in this patient group, patients with HNSCC undergoing chemoradiation treatment will have blood samples drawn using the consent procedure and infrastructure of the Liquid Biopsy Center (LBC) Biobank Head and Neck Oncology of the Cancer Center Amsterdam.

Study burden and risks

During study participation, participants will undergo one additional non-invasive MRI during treatment to obtain the imaging features.

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

1) Newly diagnosed tumours classified as stage T2-4 N0-2 located in the larynx, oropharynx or hypopharynx
(unknown primary and oral cavity are not eligible)
2) Histopathological diagnosis of invasive squamous cell carcinoma in the primary tumour
3) (Chemo)Radiotherapy planned to start within 6 weeks from baseline imaging of tumour assessment
4) No distant metastasis (M0)
5) WHO performance status 0-2
6) >= 18 years of age
7) Written informed consent signed by the patient

Exclusion criteria

Each of the following criteria will result in exclusion from participation in this study:
1) Age < 18 years
2) Pregnancy
3) Patients carrying a pacemaker, or unable to undergo an MRI on a 3T MRI scanner
4) Primary tumour of the oral cavity or unknown primary tumour
5) Prior or current anticancer treatment to the head and neck area (e.g. radical attempted or tumour
reductive surgery, neo-adjuvant or concomitant chemotherapy, EGFR inhibitors or radiotherapy),
except for endoscopic glottic laser micro surgery.
6) Current participation in any other interventional clinical study.
7) History of previous malignancy within the last 3 years.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2023
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	27-02-2024
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	NL84371.018.23