Evaluation of lymph node response with 3D-FSE CUBE imaging during chemoradiotherapy treatment of patients with head and neck squamous cell carcinoma.

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To measure changes in lymph nodes on 3D CUBE imaging during (chemo)radiotherapy of head and neck squamous cell carcinoma. By using serial imaging during treatment with a relatively short scan time, we want to establish a biological model of changes...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON37180

Source
ToetsingOnline

Brief title
EVALYM:Lymph nodes response during (chemo)radiation.

Condition

- Other condition

Synonym
Head and neck tumor Squamous cell carcinoma of the head and neck region, including the oral cavity, pharynx and larynx

Health condition

oncologie in hoofd/halsgebied

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 3D-FSE CUBE MRI imaging, head and neck tumor, lymph node response, Squamous cell carcinoma

Outcome measures

Primary outcome

Lymph nodes will be divided in a benign (< 1cm smallest axis and/or negative cytology) and a malignant (>1cm smallest axis and/or positive cytology) group. Volume change (absolute and relative) per lymph node and per patient will be calculated with a confidence interval of 95%. Treatment response is defined as a decrease in volume > 50%. Predictive value of volume decrease during (chemo)radiotherapy is defined as sensitivity, specificity, positive and negative predictive value of volume change. A ROC curve will be constructed on the basis of volume decrease between baseline and two weeks. By defining an optimal area under the curve (AUC) the optimal cut-off value of volume decrease for prediction of treatment response can be estimated.

Secondary outcome

nvt

Study description

Background summary

Imaging studies in squamous cell carcinoma and accompanied lymph node metastasis have so far focussed mainly on 2D-imaging techniques. E.g. a disadvantage is the thickness of the slices in de CT imaging, using mostly 5 mm slice thickness.[18] Therefore it is possible that measured sizes are an approach of the true size, as lymph nodes commonly vary between 3 and 10 mm in size.
3D imaging has certain advantages over 2D-imaging. When a scan is performed with isotropic voxels, it is possible to reconstruct images in all desired arbitrary planes.[23] Therefore the smallest and biggest axial diameter can be measured adequately and the volume can be determined more accurately.

Most studies were small and show heterogeneous results. Most studies have used CT. Although CT provides a good contrast between air, fat and bone, the contrast between tumor and non-tumor is difficult to visualise. MRI imaging has excellent soft tissue delineation and is therefore more suitable for tumor and lymph node imaging. [20]

Current MRI with 3D-FSE CUBE sequence provides isotropic voxels. Slices in 3D-FSE CUBE are smaller in comparison with conventional 2D imaging. Partial volume artefacts could be reduced.[24] In 3D-sequence the signal-to-noise-ratio is better compared with 2D-imaging[25] and could provide better visualisation of anatomical structures.[25, 26]
We expect that with this technique information about the location, size and shape of the lymph nodes in head and neck can be generated with a relative short imaging time.
With this technique we want to analyse the response of lymph nodes during chemoradiotherapy, more particular to analyse whether volume decrease is gradual over time.

Why is it important to assess the tumor and lymph node response during treatment?
When volume change has been assessed, a biological model that predicts response to treatment on the basis of early volume change can be realized. The best time-point during chemoradiotherapy in which to evaluate the treatment effect with imaging can be assessed.
This model allows for the possibility to predict response to therapy in an early time frame in the future. When response to therapy can be evaluated, treatment can be adjusted early in the course of treatment. Using this biological model, further possibilities of the optimal time-frame to adapt the dosage in adaptive radiotherapy can be explored.

Study objective

To measure changes in lymph nodes on 3D CUBE imaging during (chemo)radiotherapy of head and neck squamous cell carcinoma. By using serial imaging during treatment with a relatively short scan time, we want to establish a biological

model of changes in lymph nodes during radiotherapy.

Study design

This study will be a single center diagnostic study. The duration of the study will be 8 months, with an inclusion rate of 1 patient per 2 weeks.

Study burden and risks

Subjects in this study will not be at risk due to the MRI examination. The only burden that they will have is that they undergo an additional 3D-CUBE MRI in addition to the standard Baseline MRI, which takes a maximum additional scanning time of approximately 6 minutes. In the 6 weeks of radiotherapy the patient is asked to be scanned in the MRI scanner another three times at week 2, 4 and 6 weeks during radiotherapy treatment.

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

- Patients with untreated primary squamous cell carcinomas of pharynx, the oral cavity, and larynx with proven metastases in cervical lymph nodes.
- Scheduled for (chemo)radiotherapy with curative intention.
- Signed informed consent.

Exclusion criteria

carcinoma.
-Patients undergoing any other treatment option like surgery for lymph node metastasis.
-Patients with other types of head and neck malignancies: lymphatic neoplasms, esophageal malignancies, thyroid cancer, lip cancer, skin cancers and other malignancies not originating from the pharynx, laryngeal or oral cavity epithelial origin.
-Having any physical or mental status that interferes with the informed consent procedure.
-Contraindications for MRI (e.g. claustrophobia, arterial clips in central nervous system)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-09-2012
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	30-08-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL40941.078.12