

REcurrent LArynx tumor or Treatment Effects?

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To identify imaging features that can differentiate recurrent laryngeal or hypopharyngeal cancer from treatment effects after radiotherapy based on whole mount histology as reference

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

Summary

ID

NL-OMON55291

Source

ToetsingOnline

Brief title

RELATE

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym

laryngeal cancer, Recurrent laryngeal and hypopharyngeal carcinoma

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: - Diagnosis, - Imaging, - Laryngeal carcinoma, - Recurrence

Outcome measures

Primary outcome

The accuracy of DCE- and DWI-MRI based parameters based parameters in the differentiation of recurrent tumor tissue and radiation induced changes

Secondary outcome

Improvement of radiologists* delineation of tumor recurrences on imaging when given the results of this study.

The accuracy of FDG-PET and CT based parameters in the differentiation of recurrent tumor tissue and radiation induced changes.

Study description

Background summary

Early detection of recurrent laryngeal or hypopharyngeal carcinoma is crucial to improve patient prognoses. However, differentiating between post radiation treatment effects and recurrent or residual tumoral tissue is still very challenging; on imaging, recurrences are often hidden by radiation effects like edema, fibrosis or inflammation, and biopsies can give false negatives due to sampling errors.

In order to not overlook recurrences and minimize the number of unnecessary biopsies, we want to be able to accurately recognize tumors with imaging alone. This study aims to contribute to that goal

Study objective

To identify imaging features that can differentiate recurrent laryngeal or hypopharyngeal cancer from treatment effects after radiotherapy based on whole mount histology as reference

Study design

This study is a descriptive, diagnostic study that will compare imaging with whole mount histologic specimens of laryngeal and hypopharyngeal recurrences.

Study burden and risks

In the normal clinical procedure patients will undergo a DCE- and DW-MRI, sometimes supplemented with an FDGPET/CT. All imaging procedures before the total laryngectomy will be performed in a radiotherapy mask. If the MR and/or the CT scan is not available, too old (>20 days) or of insufficient quality for study purposes, or if the MRI is older than 20 days, patients will be asked to undergo additional imaging. This ensures that all patients receive a CT and MRI scan prior to treatment. If an additional CT scan is needed, patients will be exposed to radiation due to study participation.

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

- Recurrent laryngeal or hypopharyngeal carcinoma after primary radiotherapy
- Scheduled for salvage total laryngectomy
- ≥ 18 years of age
- Given informed consent

Exclusion criteria

- Patients who meet exclusion criteria for MRI at 3T as defined in the protocols of the radiology department
- Patients with contraindication for CT contrast administration 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: Diagnostic

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 31-01-2021

Enrollment: 20

Type: Actual

Ethics review

Approved WMO

Date: 28-10-2020

Application type: First submission

Review commission:	METC NedMec
Approved WMO	
Date:	22-11-2021
Application type:	Amendment
Review commission:	METC NedMec

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	NL74949.041.20