REcurrent LArynx tumor or Treatment Effects?

No registrations found.

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

Summary

ID

NL-OMON23713

Source
Nationaal Trial Register

Brief title
RELATE

Health condition

Laryngeal and hypopharyngeal carcinoma

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: Dutch Cancer Society (KWF Kankerbestrijding)

Intervention

Outcome measures

Primary outcome

Value of various imaging parameters at tumorous and non-tumorous tissue.

Secondary outcome

Improvement of radiologists' ability to delineate tumor with the outcomes of this study.

Study description

Background summary

This prospective study aims to find imaging variables that can help differentiate recurrent laryngeal or hypopharyngeal tumor tissue from tissue that has been affected by radiation.

Patients with recurrent laryngeal or hypopharyngeal cancer after radiotherapy that are scheduled for a laryngectomy will be included. Pre-surgery MRI, CT and FDG-PET imaging will be compared with whole-mount histology. The tumor outline, as determined on the pathology, can be transferred to the various in vivo imaging. Different imaging parameters will be tested for their ability to differentiate tumor tissue from treatment effects.

Study objective

This is an exploratory study, but we expect to find that the apparent diffusion coefficient on diffusion-weighted MRI and SUVmax on FDG-PET are able to differentiate between tumor tissue and treatment effects.

Study design

There are no set time points for the measurements. There is a maximum of 20 days between imaging (MRI, CT and FDG-PET) and total laryngectomy. The laryngectomy specimen immediately fixated in 4% formaldahyde, so the pathology is preserved for the comparison with the imaging.
As for the secondary outcome, delineation guidelines will be prepared based on the primary outcomes. Radiologist will be asked to delineate the tumor on the imaging of the first 10 patients. Afterwards, they will be asked to delineate the second set of 10 patients while following the delineation guidelines. Overlap between radiologists' delineation with and without guidelines, and the tumor outline as determined on the pathology will determine whether or not the guidelines improved the delineation.

Intervention

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

Recurrent laryngeal or hypopharyngeal carcinoma after radiotherapy with or without chemotherapy and scheduled for a salvage total laryngectomy. Over the age of 18. Given informed consent.

Exclusion criteria

Contraindication for MRI at 3T and/or CT contrast administration. Insulin dependent diabetes mellitus.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-01-2021
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
NA

Ethics review

Positive opinion Date:	02-11-2020
Application type:	First submission

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
NTR-new	NL9110
Other	METC UMCU : 20-617

Study results