

REcurrent LArynx tumor or Treatment Effects?

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23713

Bron

Nationaal Trial Register

Verkorte titel

RELATE

Aandoening

Laryngeal and hypopharyngeal carcinoma

Ondersteuning

Primaire sponsor: UMC Utrecht

Overige ondersteuning: Dutch Cancer Society (KWF Kankerbestrijding)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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% formaldehyde, 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.

Onderzoeksproduct en/of interventie

Not applicable

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2021
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting

NA

Ethische beoordeling

Positief advies	
Datum:	02-11-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9110
Ander register	METC UMCU : 20-617

Resultaten