

Functional outcomes of patients with T2 glottic carcinoma that were treated with radiotherapy

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We think that patients that were treated for a T2 glottic carcinoma with radiotherapy have mild-to moderate dysphonic voices, no problems with swallowing and a good quality of life.

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

Samenvatting

ID

NL-OMON22979

Bron

Nationaal Trial Register

Verkorte titel

ST_RT

Aandoening

Early glottic cancer, T2 glottic carcinoma, voice outcome, radiotherapy, radiation therapy, voice quality, voice function, quality of life

Ondersteuning

Primaire sponsor: Leiden University Medical Center

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Voice outcome

Voice quality (Voice Handicap Index questionnaire)

Voice function (maximum phonation time, fundamental frequency, dynamic range and perceptual evaluation)

Toelichting onderzoek

Achtergrond van het onderzoek

Introduction: Several studies report functional outcomes (voice function, voice quality, quality of life, and swallowing function) after treatment with radiotherapy for T1 glottic carcinoma. Patients with T1 glottic tumors show the same results, regarding the functional outcomes, after radiotherapy of transoral laser microsurgery (TLM). However, for patients with T2 tumors treated with radiotherapy, these results are not frequently described. Due to the lack of these data, we would like to perform a study to investigate the long-term functional outcomes of patients treated with radiotherapy. The objective of this study is to determine the functional outcomes (voice function, voice quality, quality of life and swallowing function) in patients who were treated with radiotherapy for a T2 glottic tumor between 2008 and 2016.

Method: a cross-sectional study will be performed, where patients will be asked to fill in two questionnaires. Furthermore, voice analysis will be performed in the outpatient clinics.

Doel van het onderzoek

We think that patients that were treated for a T2 glottic carcinoma with radiotherapy have mild-to-moderate dysphonic voices, no problems with swallowing and a good quality of life.

Onderzoeksopzet

1 time

Onderzoeksproduct en/of interventie

Questionnaires and recordings from the speech

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients treated with RT between 2008 and 2016 because of a T2 glottic carcinoma

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients with recurrent disease

Patients that are not able to read or speak Dutch

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 gestart
(Verwachte) startdatum: 01-01-2019
Aantal proefpersonen: 20
Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 24-01-2019
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45759
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7480
NTR-old	NTR7722
CCMO	NL66191.058.18
OMON	NL-OMON45759

Resultaten