

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

No registrations found.

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

Summary

ID

NL-OMON22979

Source

Nationaal Trial Register

Brief title

ST_RT

Health condition

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

Sponsors and support

Primary sponsor: Leiden University Medical Center

Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Voice outcome

Voice quality (Voice Handicap Index questionnaire)

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

Secondary outcome

Swallowing (MDADI)

Quality of Life (EORTC QLQ-C30 / HN35)

Study description

Background summary

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.

Study objective

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.

Study design

1 time

Intervention

Questionnaires and recordings from the speech

Contacts

Public

Leiden University Medical Center
Martine Hendriksma

0715261179

Scientific

Leiden University Medical Center
Martine Hendriksma

0715261179

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

Patients with recurrent disease

Patients that are not able to read or speak Dutch

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: Recruiting
Start date (anticipated): 01-01-2019
Enrollment: 20
Type: Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 24-01-2019
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45759
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results