

Functional outcome after radiotherapy for T2 glottic carcinoma

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The objective of the study is to determine the functional results (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.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Head and neck therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON45759

Source

ToetsingOnline

Brief title

Functional outcomes after radiotherapy

Condition

- Head and neck therapeutic procedures

Synonym

early glottic cancer, vocal fold cancer

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: early glottic cancer, functional outcomes, radiotherapy, voice quality

Outcome measures

Primary outcome

Voice quality

Voice function

Quality of life

Swallowing function

Secondary outcome

none

Study description

Background summary

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 or 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.

Study objective

The objective of the study is to determine the functional results (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.

Study design

A cross-sectional study, where patients will be asked to fill in two questionnaires. Furthermore, voice analysis will be performed in the

out-patient clinics.

Study burden and risks

Nature and extent of the burden: none

Risks: none

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients treated with radiotherapy for T2 glottic tumors, between 2008 and 2016 at the Leiden University Medical Center

Exclusion criteria

sign of locoregional or distant metastasis
previous radiation for head and neck tumor(s)
inability to speak or read Dutch language

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 08-01-2019

Enrollment: 30

Type: Actual

Ethics review

Approved WMO

Date: 11-12-2018

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22979

Source: NTR

Title:

In other registers

Register	ID
CCMO	NL66191.058.18
OMON	NL-OMON22979