Functional outcome of radiotherapy and laser surgery in early laryngeal carcinoma: a strategy study

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Determine the longitudinal functional toxicity profiles after laser surgery and after radiotherapy for extended T1 and limited T2 glottic carcinomas by evaluating all voice and swallowing related aspects.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Head and neck therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON33565

Source
ToetsingOnline

Brief title
FORECAST

Condition

- Head and neck therapeutic procedures

Synonym
early laryngeal carcinoma, vocal cord tumor

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,IKW/SOHA

Intervention

Keyword: CO2 laser surgery, early glottic carcinoma, functional outcome, radiotherapy

Outcome measures

Primary outcome

Voice

Swallowing

Quality of life

Secondary outcome

Utilities

Study description

Background summary

The main treatment modalities for early glottic carcinoma are radiotherapy and carbon dioxide endoscopic laser surgery (henceforth laser surgery). According to the national Dutch Guideline *Larynxcarcinoom* 2008, laser surgery is the treatment of choice for T1a superficial midcord lesions whereas radiotherapy is the gold standard for extended T1 and T2 glottic carcinomas at present. Laser surgery does have several advantages: Extra treatment steps are available in the case of recurrence, i.e. multiple laser or radiotherapy, leading to higher larynx preservation. It is also cheaper, and the treatment duration is shorter than radiotherapy. With regard to local control and laryngectomy rate in T1 and T2 glottic carcinomas, available studies provide evidence that laser is at least comparable to, and probably better than radiotherapy. However, due to a lack of comparative data concerning functional outcome (i.e. voice), the two treatments cannot be properly compared for extended T1 and limited T2 glottic carcinomas at the moment. Surgeons are not prepared to enter patients into a randomized controlled trial, because it is as yet uncertain how voice quality and voice function will be affected when these extended glottic tumors are treated with laser surgery. Preferred treatment strategy for extended T1 and limited T2 tumors can only be decided when the frequency and severity of functional toxicities have been determined and when it is known how patients value possible functional toxicities.

Study objective

Determine the longitudinal functional toxicity profiles after laser surgery and after radiotherapy for extended T1 and limited T2 glottic carcinomas by evaluating all voice and swallowing related aspects.

Study design

Prospective cohort study that has the character of an exploratory pilot study. The study has a follow-up of 2 years; measurements are taken once pre-treatment and five times post-treatment during routine clinical follow-up visits.

Intervention

Either laser surgery or radiotherapy according to the patient*s preference. For treatment with laser surgery, the tumor is assessed by the ENT surgeon during endoscopy. If the tumor meets the inclusion criteria specified for this study, and the patient has elected to be treated with laser surgery, this will take place during the same session. If laser surgery is not feasible, either because the tumor does not meet the inclusion criteria, or exposure to surgical fields is limited, the subject will be treated according to the national guideline. In most cases this will mean allocation to radiotherapy.

Study burden and risks

Burden: The burden for the individual patient is the extra time it takes (50 minutes) to complete the functional protocol (including questionnaires). Because the functional protocol is always combined with routine follow-ups, there will not be extra site visits.
Risks: Laser surgery and radiotherapy are both established routine treatment modalities. For the extended tumors, the extra risk of laser surgery will be the larger resection defect that may result in poor voice quality and function. However, this study aims at determining the frequency and severity of this risk. This study might also reveal that voice and swallowing is more of a risk after radiotherapy than has been documented before.
Benefit for the patient: Treatment choice according to preference. Laser surgery comprises shorter treatment with extra treatment options (a second laser resection or radiotherapy) in the case of recurrence. Radiotherapy is expected to have no, or only a mild effect on the voice compared to laser surgery.
Benefits in general: The relative benefits of the two treatment modalities can be compared using the outcomes of this study. Clinicians can also begin to gain insight into the trade-off between oncological and functional outcome. This may eventually lead to more individually tailored intervention. Ultimately, an acceptable toxicity profile and higher probability of larynx preservation may change laser surgery from alternative, to primary treatment for extended T1 and limited T2 glottic tumors. This in turn will be cost-saving as laser surgery is

shorter in duration and cheaper than radiotherapy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

extended T1 and limited T2 glottic laryngeal carcinoma

Exclusion criteria

- sign of locoregional or distant metastasis
- preexistent problems with voice or swallowing
- previous radiation for head and neck tumor(s)

• patients under 18 years of age
• predictable short life expectancy
• contra-indications for anesthesia
• inadequate exposure of resection area
• inability to speak or read the Dutch language
• psychological, familial, sociological or geopgraphical condition potentially hampering compliance with the study protocol and follow-up schedule

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-11-2009
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	03-11-2009
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	18-04-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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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
CCMO	NL25841.058.09

Study results

Date completed:	01-03-2015
Results posted:	07-03-2018
Actual enrolment:	68

First publication
07-03-2018