

# Proteogenomic approach to reveal age-specific molecular mechanisms of laryngeal squamous cell carcinomas

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Identify molecular differences in carcinogenesis of LSCC between younger and elderly patients through an integrated proteogenomic analysis of laryngeal tissue biopsies that could optimize personalized treatment of elderly patients in particular.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Respiratory and mediastinal neoplasms malignant and unspecified
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON46665

### Source

ToetsingOnline

### Brief title

ProLaC

### Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms

### Synonym

cancer of the voice box, Head and neck cancer, Laryngeal squamous cell carcinoma

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Keel-, neus-, oorheelkunde en hoofd-halschirurgie

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

## Intervention

**Keyword:** Elderly, Head and Neck oncology, Proteogenomics, Squamous cell carcinoma

## Outcome measures

### Primary outcome

Identify molecular differences in carcinogenesis of LSCC between younger (<70 years) and elderly (>70 years) patients through an integrated proteogenomic analysis of laryngeal tissue biopsies

### Secondary outcome

Investigate whether these molecular differences are associated with patients\* oncological outcome in terms of laryngeal preservation rate, disease-free survival, disease-specific survival and overall patient survival.

## Study description

### Background summary

With the ageing population, the incidence of laryngeal squamous cell carcinoma (LSCC) is increasing among elderly. Risk factors for LSCC in elderly are presumably different from those in younger patients, suggesting a different molecular mechanism in tumor biology. In addition, biological ageing or frailty has been related with worse treatment outcomes in patients with LSCC. A panel of tissue biomarkers could be helpful in the prediction of treatment outcome and survival of patients from different age categories and to distinguish frail elderly patients who will respond to invasive treatment from those who will not.

### Study objective

Identify molecular differences in carcinogenesis of LSCC between younger and elderly patients through an integrated proteogenomic analysis of laryngeal tissue biopsies that could optimize personalized treatment of elderly patients in particular.

## Study design

This study is a prospective observational study, following a previous pilot study on protein profiles in tissue biopsies from patients with laryngeal carcinoma (NL50497.042.14, METc-number: 2014/385). The pilot study was performed as a proof of principle to test proteogenomics in two small groups of patients with laryngeal carcinoma (young patients <65 years of age and elderly patients >75 years of age). In the current study we will extend proteogenomic analysis (consisting of mass spectrometry and RNA-sequencing) on laryngeal tissue biopsies, including patients from all age categories. Over a period of three years, a total of 144 patients will be included. The minimum duration of follow-up will be two years per included patient. Therefore, the total study duration is five years.

## Study burden and risks

Bleeding, infection and dysfonia could be possible risks of a biopsy, but are extremely rare (expected incidence < 0.1%). These complications did not occur during execution of our previous pilot study.

## Contacts

### Public

Selecteer

Hanzeplein 1  
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### Scientific

Selecteer

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Newly diagnosed squamous cell carcinoma of the larynx
- Age >18 years;
- Written informed consent;
- WHO performance status: 0-2.

### Exclusion criteria

- Previous treatment of head and neck cancer;
- Previous radiation therapy in the head and neck area;
- Diagnostic procedure in an emergency situation (e.g. severe dyspnoea);
- Histological diagnosis other than squamous cell carcinoma.

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 20-02-2019

Enrollment: 144

Type: Actual

## Ethics review

Approved WMO

Date: 08-10-2018

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

## 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	NL62246.042.17