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

Published: 08-10-2018
Last updated: 24-05-2024

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.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	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

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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