Identifying protein profile differences between laryngeal cancer of young and elderly patients: a pilot study.

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Identification of protein profile differences between laryngeal cancer of young and elderly patients. Secondary objective is to identify differences between protein interaction network in cancer and healthy tissue in young and elderly laryngeal...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON40763

Source
ToetsingOnline

Brief title
H&C-PEP

Condition

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

Synonym
cancer of the voice box, laryngeal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen (UMCG)
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Elderly, Laryngeal cancer, Proteomics

Outcome measures

Primary outcome

Identification of protein profile differences between laryngeal cancers of young and elderly patients, by comparing differential expression of proteins in cancer and healthy tissue of the same patients, determined by Liquid Chromatography Tandem Mass Spectometry (LC-MS/MS) using the Orbitrap/qTOF mass analyzer.

Secondary outcome

Identification of differences between protein interaction network in cancer and healthy tissue between elderly and young laryngeal cancer patients, determined by Liquid Chromatography Tandem Mass Spectometry (LC-MS/MS) using the Orbitrap/qTOF mass analyzer.

Study description

Background summary

Over the past years head and neck cancer (HNC) incidence is increased in the elderly population. Aetiology of HNC in young and elderly patients seems different. Excessive smoking and alcohol consumption are less often registered in elderly HNC patients. It is very likely that accumulation of spontaneous genetic mutations and an impaired immune system play an important role in developing cancer in elderly. Based on these facts, it is hypothesized that there are different molecular mechanisms in the development of HNC in young and in elderly patients. Since prognosis is also determined by molecular characteristics of the tumor, this difference could be valuable in decision making on treatment.

Study objective

Identification of protein profile differences between laryngeal cancer of young and elderly patients. Secondary objective is to identify differences between protein interaction network in cancer and healthy tissue in young and elderly laryngeal cancer patients.

Study design

Pilot study in a prospective observational cohort.

Study burden and risks

During the diagnostic procedure, one additional biopsy of the tumour will be taken for this study. Also, a biopsy of the healthy mucosa from the contralateral side of the larynx will be performed. (Temporary) dysfonia, bleeding and infection could be possible risks of a biopsy, but are extremely rare. Age criteria in both patient groups are chosen to make a clear distinction between young and elderly patients. Included patients dot not benefit from the study.

Contacts

Public
Universitair Medisch Centrum Groningen (UMCG)

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen (UMCG)

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Newly diagnosed squamous cell laryngeal cancer;
Malignancy limited to one side of the larynx;
Age <65 years (n=10) or age >=75 years (n=10);
Written informed consent;
WHO performance status 0-2.

Exclusion criteria

Age >= 65 years and < 75 years;
Previous treatment of laryngeal cancer;
Previous radiation therapy in head and neck area;
Diagnostig laryngoscopy in emergency situation.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-12-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	19-11-2014
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	NL50497.042.14