Improving the diagnosis and treatment of patients with head and neck squamous cell carcinoma: collection of tumor tissues ;The *HNcol* study

Published: 12-06-2008
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Objective:The aim of our study is to obtain a collection of head and neck squamous cell carcinomas that is well characterized for relevant clinical parameters, including follow-up.

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

Summary

ID

NL-OMON43791

Source
ToetsingOnline

Brief title
HNcol

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Upper respiratory tract disorders (excl infections)

Synonym
head and neck cancer; oral cancer

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

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

Intervention

Keyword: diagnosis, head and neck cancer, therapy, tissuebank

Outcome measures

Primary outcome

The obtained material and information will be stored and employed for future

validation and prognostic studies.

Secondary outcome

NA

Study description

Background summary

The survival of head and neck squamous cell carcinoma (HNSCC) patients has improved only minimally during the last three decades. In particular, patients with advanced disease (stage III and IV), comprising about 60% of the patient population, have a poor prognosis. Treatment options for this group are surgery followed by radiotherapy, radiotherapy alone and a combination of chemo- and radiotherapy (*chemoradiation*), sometimes followed by salvage surgery. A proportion of patients do respond to cytotoxic treatment, for a variable length of time. Study of tumor material from a large group of HNSCC patients to improve diagnosis and therapy is warranted.

Study objective

Objective:
The aim of our study is to obtain a collection of head and neck squamous cell carcinomas that is well characterized for relevant clinical parameters, including follow-up.

Study design

This is a longitudinal study in which tumor material in subsequent patient order and the clinical information regarding this material will be gathered. Sampling will last for five years. The tissues will be used in the future for

additional marker studies. The maximal storage time will be 25 years.

Study burden and risks

Extra tumor biopsies will be taken during the diagnostic work-up or a biopsies will be taken from the tumor when resected. Also a sample of venous blood will be obtained preoperatively. There is no direct benefit for the participant. The material collected will be essential for future studies that have the aim to identify tumor markers causally linked to the process of carcinogenesis and/or that are able to predict survival. These tumor markers have great future impact when used for early detection and tailored therapy.

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

1. Patients must have a histologically proven HNSCC, a squamous cell carcinoma from the oral cavity, oro- or hypopharynx, larynx and cervical part of oesophagus.
2. Patients must have sufficient knowledge of the Dutch language to understand the meaning of the study as described in the patient information.
3. Patients must have the mental capacity to understand the meaning of the study as described in the patient information patient information.
4. Patients must give written informed consent.
5. Age of the patients should be >18. An upper limit of age will not be applied. Elderly patients who are fit enough to undergo surgery in the head and neck area are not likely to encounter negative effects of the extra procedures that will be applied as part of the study.

Exclusion criteria

The decision of the surgeon that the patients is not suitable for this study (e.g. in case of limited size of the carcinoma).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-08-2008
Enrollment:	2000
Type:	Actual

Ethics review

Approved WMO

Date:	12-06-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-03-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL22230.029.08