Optical screening for head-and-neck-, lung- and esophageal cancer

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For head and neck (H&N), lung and esophageal cancer, an initial simple screening test would involve interrogation of the buccal mucosa. There are several tissue alterations related to field carcinogenesis that are currently undetectable but are...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON43773

Source
ToetsingOnline

Brief title
N.A.

Condition

- Other condition

Synonym
Lungcancer, throatcancer

Health condition

Neoplasmata in hoofd-halsgebied, longen en slokdarm

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: KWF

Intervention

Keyword: Cancer, Multi-diameters single fiber reflectance, Screening

Outcome measures

Primary outcome

Optical scattering properties of buccal mucosa will be measured and compared between patients with and without distant malignancy.

Secondary outcome

Scattering properties will be related to nanostructural changes measured using electron microscopy on biopsy material (2 mm punch) taken from the site of the optical measurement.

Study description

Background summary

Screening of the general population for early signs of cancer is the key to reduction of cancer-related death. An excellent novel opportunity for risk stratification technology development is based on the well-established phenomenon of field carcinogenesis, dictating that the genetic and environmental factors that lead to cancer development are not localized, but instead affect an organ diffusely. An individual*s risk for having cancer could hypothetically be assessed through the analysis of normal-appearing tissue from an easily accessible location that is genetically and environmentally related to the organ.

Study objective

For head and neck (H&N), lung and esophageal cancer, an initial simple screening test would involve interrogation of the buccal mucosa. There are several tissue alterations related to field carcinogenesis that are currently

undetectable but are accessible for in vivo, non-invasive optical detection. Specifically, alterations in cells due to changes in their nanoscale cellular organization (ultrastructure) have been linked to field carcinogenesis and are directly correlated to the tissue optical scattering properties. Therefore, using the light scattering properties of tissues as optical biomarkers of field carcinogenesis is a potential target for patient friendly screening.
Accurately identify the optical scattering properties of normal appearing buccal mucosa using MDSFR, in patients with histologically proven primary H&N, lung and esophageal tumours and of age matched specialism related patiënts not suspected for cancer in those organs.

Study design

Observational non-randomized cohort study with non-invasive measurements and an invasive biopsy.

Study burden and risks

The patiënt burden of the optical measurements is low. The lightsource has in intestity to low to couse any heath-related sensations. The measurement will not cause pain.
The 2mm bioptie will cause a minor burden for the patiënt. A temporary light painsensation is to be suspected. The bioptie brings a minor risk of bleading. If that occurs treatment by compression will be aplied. If necessary a soluble suture will be placed. The biopty has a very small risk of an infection. If necessary this will be treated with antibiotics.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:;Patients with cancer:
* Diagnosis of a primary, untreated
1) SCC of the oropharynx or larynx, OR
2) Lung cancer (all types and stages), OR
3) Esophageal cancer (all types and stages)
* Age 18 or over
* Good understanding of Dutch or English;Specialism-related patients not suspected for cancer
* Diagnosis of
1) (Sino)nasal polyps OR nasal septum deviation/anomaly with an extended ENT-physical examination including fiber-optical endoscopy within the last 12 months OR
2) COPD, all stages with a CT-scan within the last 12 months OR
3) Patiënts with complaints of indigestion that underwent endoscopic examination of the esophagus
* Age 50 or over
* Good understanding of Dutch or English

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study if any of the following criteria are met:;*Cancer*-patiënts:
* Prior treatment of the tumor ((chemo)radiation therapy or other)
* Another type of tumor in the head and neck region (non SCC)
* Recurrence of the tumor (no-primary tumor)
* Patients with diagnosed HIV, CMV or Hepatitis C
* Serious other illness;Specialism-related non-malignant patients:

* Any suspection of (pre)malignant laesions at physical examination and clinical tests (e.g. CT-scan and endoscopy)
* Clinical signs of malignancies (e.g. loss of weight and night sweats).
* Patients with diagnosed HIV, CMV or Hepatitis C
* Serious other illness

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-12-2015
Enrollment:	168
Type:	Actual

Ethics review

Approved WMO Date:	30-07-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-01-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-07-2016

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL53626.078.15