Diagnostic Accuracy of an Electronic Nose as Compared to Combined Conventional CT-Scanning, Autofluorescense Scopy for the Detection of Early Endobronchial Squamous Cell Cancer after prior History of Head-and-neck Cancer or Lung Cancer

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To evaluate the value of volatile organic compounds analysis by eNose in the early detection of second primaries or metastasis (and early lesions).

Ethical review	Approved WMO
Status	Pending
Health condition type	Metastases
Study type	Observational invasive

Summary

ID

NL-OMON36533

Source
ToetsingOnline

Brief title
New Techniques ENT

Condition

- Metastases
- Respiratory tract neoplasms

Synonym
Early Endobronchial Squamous Cell Cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: bronchoscopy, Electronic nose, Head-and-neck Cancer, Lung Cancer

Outcome measures

Primary outcome

Primary outcome: Identification of lung cancer, esophageal cancer or

metastasis by molecular profiling in exhaled breath and endobronchial air as

screening method in this high risk population.

Secondary outcome

Secondary outcome: Prevalence of early (microscopic) lung and esophageal cancer

in curatively treated head and neck cancer/ lung cancer patients.

Exploratory outcome: Site specific signal of pre-invasive lesions

Study description

Background summary

Given the high morbidity and mortality of clinical overt lung cancer it is suggested that early intervention is useful based on the 80% cure rate from longitudinal data and data from CT population based screening. The benefit of screening for second primary lung cancer in high risk Head and Neck Cancer patients have not been shown yet. Therefore, early detection of synchronous and metachronous tumours might be useful as early detection might lead to early intervention and therefore a better prognosis. New endoscopic imaging techniques are nowadays available for detection of early (microscopic) cancer.

Volatile breathing compounds analysis has also the potential to be a non-invasive screening technique.

Study objective

To evaluate the value of volatile organic compounds analysis by eNose in the early detection of second primaries or metastasis (and early lesions).

Study design

The study will be a prospective trial. A total of 315 patients with previous history of head-and-neck cancer and/or lung cancer are examined. Each patient will undergo upon regular follow-up fluorescence scopy and CT scanning. During bronchoscopy the bronchial tree will be inspected in the autofluorescence (AFI mode, SAFE 3000, PENTAX, Breda, the Netherlands) The esophagus will be inspected in the narrow band imaging (NBI) mode. Areas with abnormal fluorescence or NBI will be documented and biopsied. Results will be compared with volatile breathing compounds profiles obtained by exhaled air analysis and analysis of air sampled during brochoscopy from pulmonary segments closest to the tumor.

Study burden and risks

The bronchoscopy will be performed by an experienced pulmonologist. The main inconvenience for the patient is a dry cough and pain at the site of the nostril through the scoop will be introduced. These complaints are suppressed by the use of lidocaine spray. The additional images made by confocal bronchoscopy and the use of the electronic nose will add about 25 minuts to the investigation.

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

* Patients who received a curative treatment for head-and-neck or lung cancer, including all tumour stages.
* Curative treatment > 1year ago
* Smoker or ex-smoker
* Age > 18
* Written informed consent.

Exclusion criteria

* Residual cancer or recurrence at the time of screening with standard screening methods.
* Contraindications to bronchoscopy, as noted in the Dutch consensus guideline *bronchoscopy* (2003)
* Prior bronchoscopy with local treatment in the preceding two years.
* Serious non-malignant disease (e.g., congestive heart failure, or active uncontrolled bacterial, viral, or fungal infections) or other conditions that, in the opinion of the investigator, would compromise study objectives.
* Uncontrollable bleeding tendency.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2011
Enrollment:	315
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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	NL33383.018.10
Other	NTR in aanvraag