Relationship between exhaled markers and airway pathology in smokers with and without airflow obstruction

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The aim of this study is to evaluate whether there is a correlation between the sbN2-test, markers in exhaled air and the inflammatory cells in the small airways.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON34947

Source
ToetsingOnline

Brief title
Biomarkers in smokers with and without airflow obstruction

Condition

- Bronchial disorders (excl neoplasms)

Synonym
chronic bronchitis, emphysema

Research involving
Human

Sponsors and support

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

Intervention

Keyword: airflow obstruction, exhaled biomarkers

Outcome measures

Primary outcome

To demonstrate that the change in slope of the sbN2-test (phase III/IV) is correlated to an influx of inflammatory cells in the small airways (histology, morphology, immunopathology) and to inflammatory markers in exhaled breath in patients with normal and abnormal small airways function.

Secondary outcome

To demonstrate that the presence of lung cancer per se is a condition leading to a change in the breath pattern. Exhaled breath patterns will be assessed by the eNose and the differential mobility spectrometry before and after lung cancer surgery.

To assess whether there is a difference in expression of macrophage Mf1 and Mf2 markers, and in mast cell subsets (chymase/tryptase positive vs. tryptase positive) in small and large airways from patients with COPD at lung tissue level.

Furthermore we are interested whether there is a relationship between the expression of the 1,25(OH)2D3 degrading enzyme CYP24A1 and antimicrobial peptides in small and large airways in COPD patients and whether there is a correlation with local inflammation and lung function.

Study description

Background summary

Chronic obstructive pulmonary disease (COPD) is one of the leading causes of morbidity and mortality worldwide and is characterized by a fixed airflow obstruction. The cornerstone of the disease is a chronic inflammation leading to a narrowing of the small airways and thus impairing lung function. Spirometry, the most frequently used pulmonary function test for diagnosing and monitoring disease, mostly reflects obstruction in the larger airways. The single breath N2-test (sbN2-test) however is more sensitive to localize the regional heterogeneity of bronchial airflow obstruction in the small airways, the main site of injury in COPD.

Study objective

The aim of this study is to evaluate whether there is a correlation between the sbN2-test, markers in exhaled air and the inflammatory cells in the small airways.

Study design

This protocol describes a cross-sectional, explorative trial in at least 16 patients with COPD (up to GOLD III) and 8 patients without COPD who are scheduled for surgical resection for primary lung cancer. Immunohistological methods will be used to characterize the airways (large and small) inflammation pattern in macroscopically normal tissue containing small and large airways collected from sites distant from the tumor. Inflammatory markers will be measured in exhaled breath (exhaled breath condensate, exhaled NO) and be correlated to the sbN2 test. Breath patterns before and after lung cancer surgery will be assessed by the electronic nose and differential mobility spectrometry.

Study burden and risks

The collection of exhaled air is of no burden and risk for the participation in this study. Pulmonary function tests are performed by all patients who are scheduled for lung cancer surgery and therefore this is information available from clinical practice. There is no direct benefit for the patient to participate in this study.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Male or female subject, age > 40 years, current or ex-smokers
- Plannend lung resection for primary lung cancer of any size.
- COPD: irreversible airflow limitation (postbronchodilator FEV1/FVC < 70% according to GOLD guidelines).
- non-COPD: FEV1/FVC >70%
-Written informed consent.

Exclusion criteria

-Patients with a history of asthma or other active lung disease.
-Lung resection for other reasons than lung cancer (e.g. infective diseases like

bronchiectasis).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-10-2010
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	20-04-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL31666.058.10