Feasibility of fibered confocal fluorescence microscopy (FCFM) in patients with pulmonary diseases.

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To explore the potential of FCFM by comparing images of the bronchial wall in patients with different pulmonary diseases to pathology specimens of the same area of the bronchial wall.

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

Summary

ID

NL-OMON32614

Source
ToetsingOnline

Brief title
FCFM in patients with pulmonary diseases.

Condition

- Bronchial disorders (excl neoplasms)

Synonym
pulmonary diseases

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, FCFM, Pulmonary disease

Outcome measures

Primary outcome

The microscopic autofluorescence structure of normal and pathologic bronchial mucosae will be analysed. Pathology specimens will analyzed by a pathologists with expertise in pulmonary disorders. Characteristics of images will be defined, and related to the pathological findings.

Secondary outcome

NA

Study description

Background summary

Fibered confocal fluorescence microscopy is a new technique that produces microscopic imaging of a living tissue through a 1-mm fiberoptic probe that can be introduced into the working channel of the bronchoscope. The aim of the present study is to investigate the feasibility of this new technique in patients with various pumonary diseases

Study objective

To explore the potential of FCFM by comparing images of the bronchial wall in patients with different pulmonary diseases to pathology specimens of the same area of the bronchial wall.

Study design

A descriptive feasibility study, in which confocal imaging will be recorded and bronchial biopsies will be taken during the same bronchoscopy session in well-characterized patients with an indication for bronchoscopy for varying reasons

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 will add about 10 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

Adult patients (18-75 yr) with the following pulmonary diseases will be studied:
1. three patients with a peripheral lung tumor who undergo bronchoscopy as part

of the routine assessment
2. three patients with a previous diagnosis or clinical suspicion of sarcoidosis.
3. three patients with COPD (GOLD II-IV) (smokers or ex-smokers, postbronchodilator (after inhalation of 400 mcg salbutamol) FEV1/FVC <70%, reversibility <9%)
4. three patients with asthma (nonsmokers, reversibility of FEV1 > 12% after inhalation of 400 mcg salbutamol)

Exclusion criteria

Patients who are > 80 years of age or who have previously undergone radiotherapy will be excluded.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2008
Enrollment:	12
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	NL25751.018.08