

# Comparison of fibered confocal fluorescence microscopy (FCFM) to histology

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The aim of this study is to compare (normal) histology to the images obtained by FCCM in marked sites.

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

## Summary

### ID

NL-OMON33013

### Source

ToetsingOnline

### Brief title

FCFM in lobectomy or pneumectomy.

### 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, Lobectomy, Pneumonectomy

## Outcome measures

### Primary outcome

The microscopic autofluorescence structure of normal and pathologic bronchial mucosae will be analysed using real-time image reconstruction and video mosaicing techniques. Pathology specimens will analyzed by a pathologist 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 correlate histology to the images obtained.

### Study objective

The aim of this study is to compare (normal) histology to the images obtained by FCCM in marked sites.

### Study design

A descriptive 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 surgery. During general anesthesia, confocal imaging is performed at lobair carinae, first bronchial generation, bronchiole, alveoli in three different segments. After imaging, peripheral biopsy is taken and the surgery procedure will proceed. Markings of

biopsy site will be set using methylene blue dye.

### **Study burden and risks**

The bronchoscopy will be performed, after the general anesthesia, by an experienced pulmonologist. The studied extra investigation is confocal microscopy with taking of biopsies, adding extra time (about 10 minutes) to the procedure.

## **Contacts**

### **Public**

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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 undergo surgical procedure (lobectomy or pneumectomy)

## Exclusion criteria

1. Only bullae on CT scan in lobectomy area
2. Severe interstitial lung disease
3. Patients who are pregnant
4. Previously radiotherapy on the surgery specimen.

## 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): 01-04-2009

Enrollment: 6

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	NL27181.018.09