Validation of optical frequency domain imaging (OFDI) bronchoscopy as a diagnostic imaging modality to characterize pulmonary lesions

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To validate OFDI bronchoscopy as a diagnostic imaging modality to characterize pulmonary lesions.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON43636

Source
ToetsingOnline

Brief title
OFDI in Lung Cancer

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
Lung cancer, non-small cell lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: FOM

Intervention

Keyword: Bronchoscopy, Lung Cancer, Optical coherence tomography

Outcome measures

Primary outcome

correlate OFDI imaging to histopathology, thereby developing image criteria to

identify pathology in OFDI images

Secondary outcome

NA

Study description

Background summary

Pulmonologists are increasingly confronted with endobronchial and parenchymal lesions that are suspected for malignancy. A major cause for this is the increase in radiological imaging of the thorax for lung cancer screening purposes and in the workup of other diseases (i.e. pulmonary embolism, infection and other cancers). Invasive diagnostic procedures to characterise these lesions, like biopsy or surgical resection, are not without risk. The alternative, follow-up by computed tomography, takes up to two years to complete, thereby causing uncertainty for patients and exposing them to radiation and delay of treatment in case a lesion is malignant. Recently we developed a new bronchoscopic catheter that incorporates an imaging technique called optical frequency domain imaging (OFDI). This technique enables the characterization of pulmonary lesions at microscopic resolution.

Study objective

To validate OFDI bronchoscopy as a diagnostic imaging modality to characterize pulmonary lesions.

Study design

non-randomized non-blinded, non-sham controlled pilot study.

Study burden and risks

OFDI is a minimally invasive technique. The catheter is blunt and does not penetrate the mucosa, but only gently comes in contact with the mucosa. The bronchoscopic procedure will be done as part of routine clinical care. The extra time needed to image the lesion with OFDI is estimated to be 5 minutes.

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

Patiënts with lung cancer or who are suspected of having lung cancer

Exclusion criteria

Unable to undergo bronchoscopy

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):	12-09-2016
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	OCT catheter
Registration:	No

Ethics review

Approved WMO

Date:	01-06-2016
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	NL52698.029.15