CLE and OCT in diagnosing ILD, a comparison with imaging and pathology.

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To identify and define characteristics of ILD on the pCLE and pOCT image of airway wall mucosa and the alveolar compartment and compare this to HRCT imaging and pathology.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Observational invasive

Summary

ID

NL-OMON42794

Source
ToetsingOnline

Brief title
Optical biopsy for diagnosing ILD

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
ILD Interstitial lung disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Legaat

Intervention

Keyword: CLE, ILD, OCT

Outcome measures

Primary outcome

- To describe and develop visual descriptive image criteria for pCLE images of the alveolar compartment in ILD

- To describe and develop visual descriptive image criteria for pCLE images of airway wall mucosa in ILD

- To obtain quantitative measures of the alveolar compartment in ILD by pCLE imaging (cellularity, fluorescence, size of opening alveolar duct (µm))

- To develop descriptive image criteria and a classification of pOCT images of the alveolar compartment in ILD

- To obtain quantitative measures of the alveolar compartment in ILD by pOCT imaging (size of alveolar duct openings, fiber thickness)

Secondary outcome

- Assessing procedure-related adverse events of pCLE and pOCT

- Assessing technical feasibility of pCLE and pOCT

- To develop an CLE and OCT image atlas for sarcoidosis in mucosa and the alveolar compartment

- To conduct exploratory breathprints from ILD patients by electronic nose, for the purpose of building a breathcloud

Study description

Background summary

Interstitial lung disease (ILD), refers to a group of lung diseases affecting the interstitium, causing stiffness of the lungs and impaired gas exchange due

to inflammation and changes in the extra-cellular matrix composition of the alveolar septae. Often, assessing a classifying diagnosis provides a diagnostic challenge. Currently HRCT, endoscopic or surgical (VATS) assessment including lung biopsies are diagnostic tools for patients with suspected ILD. However, tissue acquisition is associated with morbidity in these patients with an already compromised pulmonary function. The aim of the study is to examine whether the addition of novel optical techniques to the diagnostic process of ILD can limit the need for a tissue (surgical) diagnosis and reduce the sampling error rate of biopsies by providing additional information on biopsy location.

Novel probe based optical techniques such as Confocal laser endomicroscopy (pCLE) and Optical coherence tomography (pOCT) are non-invasive optical techniques, compatible with conventional diagnostic bronchoscopes and provide non-invasive, real-time information on the airway wall and the alveolar compartment. Therefore, immediate validation of optical measurements during a biopsy is possible. Optical techniques might either obviate the need for an tissue biopsy or improve the diagnostic yield of conventional biopsy methods and make surgical lung biopsies that are associated with high morbidity and costs redundant.

Study objective

To identify and define characteristics of ILD on the pCLE and pOCT image of airway wall mucosa and the alveolar compartment and compare this to HRCT imaging and pathology.

Study design

This is an investigator-initiated, observational study in 20 ILD patients. For this study we conduct pCLE and pOCT imaging of the alveolar compartment of ILD patients with an indication for cryobiopsy. In patients who have an additional indication for biopsies of the airway wall mucosa (EBB), we will also conduct pCLE and pOCT imaging of the airway wall mucosa. Before the bronchoscopic procedure an exploratory breathprint will be obtained by electronic nose for the purpose of building a breathcloud. This will be recorded and processed by R. de Vries. according to the study: de Vries et al, 'Integration of Electronic Nose Technology with Spirometry: Validation of a New Approach for exhaled Breath Analysis', currently revised for Journal of Breath Research.

Study burden and risks

A participating patient will not benefit from this study. However the results of this study may benefit the diagnostic procedure of future ILD diagnostics and may improve quality of life of future ILD patients. The procedure of bronchoscopy combined with the novel non-invasive, probe based, optical

techniques in the airways and the alveolar compartment have proved to be safe and provide real time information on a microscopic level regarding tissue architecture. There is little burden related to study participation: during the conventional bronchoscopic procedure, optical pCLE and pOCT measurements with the use of a light beam will be performed by holding the probe in perpendicular contact with the tissue, followed by conventional cryobiopsy and/or EBB (routine work up) at the same site as the CLE/ OCT measurements, without the need for additional biopsies for research purposes. Estimated prolonged bronchoscopy time due to imaging is 5 to 10 minutes. The patient will not notice anything due to the use of propofol sedation (part of standard protocol). Adverse advents are not expected, based on our own OCT experience in the TASMA trial (asthma patients), and the data of previous studies where bronchoscopy combined with probe based optical techniques are reported to be safe, easy to perform and little time-consuming, without adverse events. In conclusion, in our opinion the burden and risks associated with the additional probe based optical technique measurements are neglectible.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- *18 years of age
- Supected ILD and referred for diagnostic bronchoscopic procedure with cryobiopsy

Exclusion criteria

- Smoked in the last 6 months - Inability and willingness to provide informed consent
- Inability to comply with the study protocol

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):	19-10-2015
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Optical coherence tomography
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-09-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-01-2016
Application type:	Amendment
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	NL54612.018.15