New optical techniques in interstitial lung disease

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To identify and define ILD characteristics with innovative imaging by confocal laser endomicroscopy (CLE), optical coherence tomography (OCT) and higher harmonic generation microscopy (HHGM)

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

Summary

ID

NL-OMON55811

Source
ToetsingOnline

Brief title
New optical techniques in ILD

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
Diffuse Parenchymal Lung disease, Interstitial lung disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Confocal laser endomicroscopy, Higher harmonic generation microscopy, Interstitial lung disease, Optical coherence tomography

Outcome measures

Primary outcome

-To describe visual qualitative characteristics of CLE, OCT and HHGM images of the alveolar compartment and the airway wall in ILD

-To obtain quantitative measurements of ILD by analysis of the CLE, OCT and HHGM imaging of the alveolar compartment (size of the alveoli (um), thickness of the alveolar septum)

-To compare the CLE, OCT and HHGM images with pathology results

-To identify specific structures and cells (i.e. collagen fibres, elastin, inflammatory cells) on HHGM images of lung tissue

-To identify specific structures and cells (i.e. collagen fibres, elastin, inflammatory cells) on HHGM images in ILD

Secondary outcome

-To create an image atlas with pOCT, pCLE and HHGM images of the airway wall and alveolar compartment in ILD

-Assessing procedure-related adverse events of pCLE and pOCT

-Assessing technical feasibility of pCLE, pOCT and HHGM

-To assess the timeframe that is necessary for adequate HHGM images of lung tissue in ILD

Study description

Background summary

Reaching classifying diagnosis in interstitial lung disease (ILD) can be a challenge. When patients history, laboratory tests and HRCT are not sufficient to reach confident final diagnosis the next step is tissue acquisition. However, this means an invasive procedure with the risk of adverse events in a vulnerable patient group. In this study we examine three novel optical techniques to visualize lung tissue on (near)microscopic level. These techniques have the potential to add crucial information (i.e. fibrotic versus non-fibrotic ILD) to the multi-disciplinary team discussion and therefore reduce the need for invasive diagnostic procedures.

Study objective

To identify and define ILD characteristics with innovative imaging by confocal laser endomicroscopy (CLE), optical coherence tomography (OCT) and higher harmonic generation microscopy (HHGM)

Study design

This is an investigator-initiated, observational study in 15 ILD patients

Study burden and risks

We expect patient sedation time to be prolonged by 10 minutes because of the OCT and CLE measurements.
Based on our experiences with CLE and OCT in previous AMC initiated trials, and literature where CLE and OCT measurements of the airway wall and alveolar compartment are obtained, we state that imaging by CLE and OCT is safe and poses no risk for the patient.
Images made by HHGM are ex-vivo and thereby are of no burden or risk to the patients.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1100 DD
NL

Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1100 DD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Interstitial lung disease patients with an indication for lung tissue sampling

Exclusion criteria

* Inability and willingness to provide informed consent
* Inability to comply with study protocol
* Use of clopidogrel, or other new anti-platelet therapy, or anticoagulant drugs that cannot be stopped temporarily
* Thrombocytopenia < 70x10^9
INR > 1.3
* Pregnancy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-11-2019
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	18-11-2019
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	NL66873.018.18