CLE and OCT in acute respiratory insufficiency

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To identify the characteristics on pCLE and OCT images of the alveolar compartment in mechanically ventilated critically ill patients with non-resolving acute respiratory failure.

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-OMON47517

Source
ToetsingOnline

Brief title
CLEOpaTra-study

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
Non-resolving acute respiratory insufficiency in mechanically ventilated patients

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Acute respiratory insufficiency, Confocal Laser Endomicroscopy, Mechanically

ventilated patients, Optical Coherence Tomography

Outcome measures

Primary outcome

- Assessing technical feasibility of pCLE and OCT of various

(diseased/non-diseased on HR-CT-scan) alveolar compartments in mechanically

ventilated patients. (% of successful videos/time for procedure (min))

- Assessing procedure-related adverse events of pCLE and OCT

Secondary outcome

- To compare the pCLE/OCT imaging with the radiological patterns

- To compare the pCLE/OCT-imaging with the histopathology (where available)

Study description

Background summary

Acute respiratory distress syndrome is a severe complication of critical illness. The diagnosis of ARDS is difficult, and it could be important to differentiate ARDS from other causes of acute respiratory failure. Histopathology would help treatment decisions but is not available, due to morbidity and mortality risks. Innovative probe-based imaging techniques such as *Confocal Laser Endomicroscopy* (CLE) and *Optical Coherence Tomography* (OCT) are high-resolution optical techniques that, combined with conventional bronchoscopy, have been found to provide minimal-invasive, real-time, near-histology information about the alveolar compartment in non-ventilated non-critically ill patients.

Study objective

To identify the characteristics on pCLE and OCT images of the alveolar compartment in mechanically ventilated critically ill patients with

non-resolving acute respiratory failure.

Study design

This is an investigator-initiated observational in-vivo study, with an explorative character. We will enroll a maximum of 20 patients with non-resolving acute respiratory failure mandating a bronchoscopy (the researchers decide which patient is eligible, based on the heterogeneity of the disease and the suspected etiology). One patient can be imaged several times, on condition there is an indication for bronchoscopy.
Patients will receive additional optical pCLE and pOCT measurements of the alveolar compartment with a total estimated time for research measurements of 5-10 minutes.

Study burden and risks

Patients in this study will not benefit from participation. There is little to no burden related to study participation. During a standard diagnostic bronchoscopy with broncho-alveolar lavage, optical pCLE and OCT measurements with the use of a light beam will be performed by holding the probe in perpendicular contact with the tissue, a procedure that will last approximately 5-10 minutes. Obviously, OCT and CLE measurements will only be obtained in the absence of mechanical ventilation problems during bronchoscopy. Patients will not notice this as they are sedated. Adverse events are not expected based on our own OCT and CLE experience in interstitial lung disease (ILD) patients (Clinicaltrial.gov identifier NCT02689102, AMC protocol nr NL54612.018.15), which is in concordance with the literature, where bronchoscopy combined with probe-based optical techniques in non-ventilated patients was 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 neglectable.

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

- *18 years of age
- Admitted to the intensive care unit of the Academic Medical Center
- Non-resolving acute respiratory failure mandating a standard diagnostic bronchoscopy with broncho-alveolar lavage

Exclusion criteria

- Inability and willingness to provide informed consent by family-members
- 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):	11-10-2017
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Confocal Laser Endomicroscopy and Optical Coherence Tomography
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-06-2017
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	NL61112.018.17