Confocal lAser EndomicroScopy in patients with non-resolving Acute Respiratory failure

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To identify the characteristics on CLE images of the alveolar compartment in mechanically ventilated COVID19 patients with non-resolving acute respiratory failure.

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

Summary

ID

NL-OMON51162

Source
ToetsingOnline

Brief title
CAESAR

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
acute respiratory distress syndrome, 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: Ministerie van OC&W,MaunaKea Technologies, Paris, France

Intervention

Keyword: Acute respiratory insufficiency, Confocal laser endomicroscopy, COVID19, Mechanically ventilated

Outcome measures

Primary outcome

identification of specific CLE patterns of the alveolar compartment of COVID 19

invasivally ventilated patients

Secondary outcome

-Description of how CLE patterns change over time within the same patients

- Descriptive correlation of CLE patterns with Chest CT

- Descriptive correlation of CLE patterns with lung ultrasound

- Descriptive correlation of CLE patterns with cytology from bronchoalveolar

lavage

-Descriptive correlation of in vivo CLE patterns with histology (when available)

-Descriptive correlation of ex vivo CLE images with histology (when available)

-Time of procedure

- Proportion of successful imaging of alveolar compartment

Study description

Background summary

Acute respiratory distress syndrome (ARDS) is an infrequent but severe complication of COVID 19. The clinical syndrome of ARDS form a heterogeneous group of patients with varying underlying pathophysiology, of which some develop pulmonary fibrosis. COVID 19 patients with ARDS might even be more prone to developing fibrosis due to prolonged need for mechanical ventilation. Identification of patients with fibrotic changes in an early stage might influence therapeutic management, but is challenging using current diagnostics.

The innovative probe-based imaging techniques *Confocal Laser Endomicroscopy* (CLE) is a high-resolution optical technique that, combined with conventional bronchoscopy, has been found to provide real-time, near-histology information about the alveolar compartment in both non-ventilated and (intubated) critically ill patients.

Study objective

To identify the characteristics on CLE images of the alveolar compartment in mechanically ventilated COVID19 patients with non-resolving acute respiratory failure.

Study design

investigator-initiated, observational study in 15 mechanically ventilated critically ill patients with non-resolving acute respiratory failure.

Study burden and risks

Patients in this study will not benefit from participation. There is little to no burden related to study participation. Bronchoscopy with bronchoalveolar lavage (BAL) is part of the standard diagnostic clinical care. For study purposes, the clinically indicated bronchoscopy with be combined with CLE imaging in the same session. This lengthens the standard procedure with 2 to 4 minutes. Since ICU patients are sedated as a part of standard ICU care, patients will be unaware of the CLE imaging. Adverse events are not expected based on our own CLE experience in ARDS patients and interstitial lung disease (ILD) patients 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 negligible.

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
- 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
-ECMO
- 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:	Recruiting
Start date (anticipated):	03-03-2021
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	02-02-2021
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	NL76007.018.20