Bedside exhaled breath octane measurements for the diagnosis and monitoring of acute respiratory distress syndrome in invasively ventilated patients

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21219

Source
Nationaal Trial Register

Brief title
DARTS

Health condition

Acute respiratory distress syndrome

Sponsors and support

Primary sponsor: Amsterdam UMC location AMC
Source(s) of monetary or material Support: Dutch longfoundation (Longfonds) and Health Holland through the Public-Private-Partnership.

Intervention

Outcome measures

Primary outcome

Primary independent variable
Exhaled breath concentration of octane, measured by compact gas- chromatography.

Primary dependent variable
ARDS as defined by the Berlin definition. The variable ARDS will be defined in three ways, ARDS as defined by the clinician, ARDS as defined by the researcher and ARDS as defined by an expert panel. The expert panel will provide a label of uncertainty to their decision.

Primary outcome
Optimal sensitivity and specificity and cutoff for breath octane concentration in diagnosis of ARDS.

Secondary outcome

Secondary independent variables
• Volatile organic compounds in exhaled breath measured by gas- chromatography and mass-spectrometry.
• Protein patterns (including but not limited to total protein, myeloperoxidase (MPO) and matrix metalloproteinase (MMP-9)) in fluid from the heat-moist exchanger.
• Non-invasive imaging techniques: Lung ultrasound and Electrical impedance tomography.
• Lung injury prediction score.

Secondary dependent variables:
• Therapeutic response in ARDS patients is defined as an improvement in PaO2/FiO2 24 hours after inclusion.
• ARDS phenotypes defined by clinical characteristics (pulmonary / non- pulmonary cause) and by a four biomarker profile of plasma biomarkers (reactive / non-reactive).

Other study parameters
• Chronic co-morbidities and medication.
• Acute physiology and chronic health evaluation score [33].
• ICU mortality, hospital mortality, 30– and 90–day and 1 year mortality.
• For selected patients, who give explicit permission: assessment of long term physical and mental functioning.

Study description

Background summary

Rationale: The acute respiratory distress syndrome (ARDS) is a severe complication of critical

illness characterized by acute onset, protein rich, pulmonary edema and is associated with mortality rates above 40%. Early diagnosis and monitoring are major challenges. Objectives: (1) To evaluate the diagnostic accuracy of a point of care octane breath test for ARDS in intubated and mechanically ventilated ICU patients; (2) to evaluate the association between changes in exhaled octane concentrations and changes in the clinical characteristics of patients with ARDS; and (3) to compare the diagnostic and predictive (additive) accuracy of several non-invasive tests for ARDS.
Study design: Observational cohort study with serial measurements.
Study population: Consecutive intubated and mechanically ventilated ICU patients.
Main study parameters/endpoints: Primary parameter: octane concentrations in exhaled breath; secondary parameters: spectrum of volatile organic compounds in exhaled breath measured by gas-chromatography and mass-spectrometry, levels of biomarkers of inflammation and lung injury in condensate samples and plasma, and non-invasive imaging techniques including lung ultrasound and electrical impedance tomography. Primary endpoint: diagnostic accuracy of octane concentrations in exhaled breath, as quantified by the area under the receiver operating characteristics curve.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will experience no risk from participation in the study but will also not benefit. Several hundreds of patients have been subjected to collection of exhaled breath without any adverse events. As part of routine clinical care heat-moist-exchanger (HME) will be collected, to obtain the filter fluid. Also plasma biomarkers will be determined, to predict the biological phenotype. Lung ultrasound and electrical impedance tomography are routinely performed in the participating centers and expose no risk to the patients. Intubated and mechanically ventilated ICU patients may benefit from the results from this study in the future, as it could result into a new diagnostic test for ARDS.

Study objective

Primary hypothesis:
Octane concentrations in exhaled breath facilitate early detection of ARDS in ICU patients.

Secondary hypotheses:
- ARDS resolution is associated with a decrease in octane in exhaled breath.
- Additional biomarkers of ARDS can be identified in exhaled breath through GC-MS.
- There is an additive predictive value of octane to other non-invasive diagnostic tests, such as the lung injury prediction score, assessment through lung ultrasound and electrical impedance tomography.
- Non-invasive diagnostic tests, including but not limited to biomarkers in plasma and HME fluid and parameters from EIT and LUS images, can be used to discriminate between ARDS phenotypes.

Study design

Patients will be assessed at least two time points. The first assessment is within 48 hours after intubation and start of ventilation. The second assessment is 24 hours later. Several parameters that are collected as part of standard clinical practice will be recorded in the online case record file; airway pressures, arterial blood gas analysis, lung and cardiac

ultrasound and electrical impedance tomography. Lung ultrasound and EIT will be performed in patients with respiratory failure if more than one patient is included at the same time. Several waste materials are collected for the purpose of research only: exhaled breath, waste blood from arterial blood gas analysis and heat-moist exchanger from the ventilator circuit. If the patient was diagnosed with ARDS at one of the first two time points, three additional breath samples will be taken. At 48 hours, 96 hours and 2 weeks after the first assessment, only if the patient is still ventilated in the ICU. During the third assessment, LUS is also repeated.

Intervention

None

Contacts

Public
AMC
Lieuwe Bos

-
Scientific
AMC
Lieuwe Bos

-

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Invasively ventilated.
• Admitted to one of the participating ICUs.
• Expected to receive invasive mechanical ventilation for at least 24 hours.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

• Expected to be deceased within 24 hours at the moment of inclusion.
• Received invasive ventilation for more than 48 hours at any moment in the 7 days preceding the moment of inclusion.
• Exhaled breath collection deemed inappropriate by the attending physicians.
• Tracheostomy.
• Active withdrawal from the study by the patient.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2019
Enrollment:	500
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-12-2019
Application type:	First submission

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
NTR-new	NL8226
Other	METC AMC and METC MUMC : W18_311

Study results