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

Gepubliceerd: 11-12-2019 Laatst bijgewerkt: 13-12-2022

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…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21219

Bron
Nationaal Trial Register

Verkorte titel
DARTS

Aandoening

Acute respiratory distress syndrome

Ondersteuning

Primaire sponsor: Amsterdam UMC location AMC
Overige ondersteuning: Dutch longfoundation (Longfonds) and Health Holland through the Public-Private-Partnership.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

AMC
Lieuwe Bos

-

Wetenschappelijk

AMC
Lieuwe Bos

-

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2019
Aantal proefpersonen:	500
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	11-12-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8226
Ander register	METC AMC and METC MUMC : W18_311

Resultaten