An electronic nose in the intensive care investigation of acute lung injury and acute respiratory distress syndrome.

No registrations found.

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

Summary

ID

NL-OMON27329

Source
Nationaal Trial Register

Brief title
NICI study

Health condition

ALI, ARDS, eNOSE, sepsis, mechanical ventilation.
ALI, ARDS, eNOSE, sepsis, beademing.

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Departments of Pulmonology and Intensive Care.
Source(s) of monetary or material Support: fund=initiator=sponsor.

Intervention

Outcome measures

Primary outcome

Electronic nose smellprint.

Exhaled air is collected via a connector in the circuit of the mechanical ventilator near the tube and, if present, proximal to the filter. The connector is attached to the electronic nose (Cyranose 320) and measurements are taken for 60 seconds.

When exposed to a gas mixture, the sensors of the electronic nose will swell and thus change the electrical conductance, resulting in a unique smellprint.

Secondary outcome

- Lung injury score.

Study description

Background summary

Critically ill patients may develop acute lung injury (ALI) or its more severe form acute respiratory distress syndrome (ARDS), which can be the result of either a pulmonary insult (e.g., pneumonia) or indirect injury (e.g., sepsis). Early and adequate recognition of ALI/ARDS is mandatory for intensive care physicians to take sufficient actions at the right time. In today’s intensive care practice, ALI/ARDS is diagnosed and monitored by clinical symptoms, radiology findings and laboratory measurements.

However, diagnosing ALI/ARDS remains challenging. Exhaled breath molecular profiling using electronic nose technology can potentially be usefull in diagnosing as well as monitoring lung injury in mechanically ventilated patients.

Study objective

1. We postulate that an electronic nose can discriminate exhaled breath of patients with ALI/ARDS lung injury from patients without lung injury and without being at risk for developing lung injury

2. We postulate that an electronic nose can recognize worsening or improvement of lung injury in patients at risk for ALI/ARDS

3. We postulate that an electronic nose can predict the development of ALI/ARDS in patients at risk for ALI/ARDS

Study design

The electronic nose will measure the exhaled breath of the included patients once every day.

Intervention

No interventions, diagnostic study.

Contacts

Public
Clinical Research Fellow 'Electronic Nose'
Academic Medical Center (AMC)
University of Amsterdam
Department of Pulmonology
 F5-260
P.O.Box 22660
Niki Fens
Meibergdreef 9

1100 DD
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5664359
Scientific
Clinical Research Fellow 'Electronic Nose'
Academic Medical Center (AMC)
University of Amsterdam
Department of Pulmonology
 F5-260
P.O.Box 22660
Niki Fens
Meibergdreef 9

1100 DD
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5664359

Eligibility criteria

Inclusion criteria

1. Patients with established ALI/ARDS according to the American/European Consensus Criteria

2. Patients at risk for developing ALI/ARDS

3. Patients without lung injury, not at risk for developing ALI/ARDS and not known to a have pre-existent pulmonary condition

Exclusion criteria

1. Younger than 18 years of age

2. Pregnancy

3. Current malignancy

4. Use of steroids in higher than hysiologic dosages (300 mg hydrocortisone or equivalent)

5. Recent cardiopulmonary surgery (reason for admittance)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2008
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-11-2008
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	NL1488
NTR-old	NTR1558
Other	METC AMC : AMC20080915.1
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A