BREathprint Variation during Intubation, mechanical ventilation and Anesthesia.

No registrations found.

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

Summary

ID

NL-OMON24277

Source
NTR

Brief title
BREVIA

Health condition

Ventilator associated lung injury

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam
Source(s) of monetary or material Support: Academic Medical Center, Amsterdam

Intervention

Outcome measures

Primary outcome

1. Breathprint (exhaled biomarkers) as obtained by electronic nose measurement (Cyranose and ContiNose);

2. Systemic biological markers of oxidative stress and lung injury (e.g. Urin acid, IL-1b, IL-6, IL-8, TNFa en MPO).

Secondary outcome

N/A

Study description

Background summary

Exhaled human breath contains thousands of volatile organic compounds (VOCs) in gas phase. Electronic noses (eNoses) produce breathprints based on VOCs using an array of different sensors. Subsequently, these breathprints can be analyzed and used for diagnostic purposes.
It is uncertain whether intubation and mechanical ventilation per se influence breathprints.

Objective:

The goal of the present investigation is to determine breathprint variation in intubated and mechanically ventilated patients without pre–existing lung injury before, during and after short–term intubation and mechanical ventilation.

Study design:

Prospective observational study.

Study population:

Twenty–five patients without preexisting lung injury, who need short–term intubation and mechanical ventilation. For this we choose to include patients scheduled for elective surgery.

Main study endpoints:

1. Breathprint (exhaled biomarkers) as obtained by electronic nose measurement (Cyranose and ContiNose);

2. Systemic biological markers of oxidative stress and lung injury.

Data analysis:

1. Principal component analysis to extract discriminative features from the large-dimensional dataset;

2. Independent samples t-test for difference in breathprints between before intubation and after mechanical ventilation;

3. Pearson’s Correlation coefficient for correlations between breathprints and oxygenation parameters, systemic biological markers.

Study objective

1. Breathprints, generated by an electronic nose, variate during mechanical ventilation;

2. Breathprints correlate with biological markers for oxidative stress and lung injury during mechanical ventilation.

Study design

Both exhaled as systemic biomarkers are collected before, during and after operation. During operation breathprints are continuously obtained by ContiNose and are measured once an hour by Cyranose. Blood is collected every hour.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. Planned elective surgery (with planned intubation >5h);

2. Informed consent;

3. Anesthesia with intravenous anesthestics.

Exclusion criteria

1. < 18 years of age;

2. History of any chronic or acute pulmonary condition (asthma, COPD, CF, pulmonary malignancy or acute lung injury);

3. Intubation and mechanical ventilation within the last 7 days.

Study design

Design

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

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2011
Enrollment:	25
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-02-2011
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	NL2621
NTR-old	NTR2749
Other	MEC AMC : 10/262
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A