

BREathprint Variation during Intubation, mechanical ventilation and Anesthesia.

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1. Breathprints, generated by an electronic nose, vary during mechanical ventilation; 2. Breathprints correlate with biological markers for oxidative stress and lung injury during mechanical ventilation.

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

Samenvatting

ID

NL-OMON24277

Bron

Nationaal Trial Register

Verkorte titel

BREVIA

Aandoening

Ventilator associated lung injury

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam

Overige ondersteuning: Academic Medical Center, Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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 (Cyrano 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.

Doel van het onderzoek

1. Breathprints, generated by an electronic nose, vary during mechanical ventilation;
2. Breathprints correlate with biological markers for oxidative stress and lung injury during mechanical ventilation.

Onderzoeksopzet

Both exhaled and 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.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Planned elective surgery (with planned intubation >5h);
2. Informed consent;
3. Anesthesia with intravenous anesthetics.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2011
Aantal proefpersonen:	25
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	11-02-2011
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	NL2621
NTR-old	NTR2749
Ander register	MEC AMC : 10/262
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A