# BreathDx – Molecular Analysis of Exhaled Breath as a Diagnostic Test for Ventilator–Associated Pneumonia

Gepubliceerd: 28-10-2016 Laatst bijgewerkt: 13-12-2022

1) Molecular analysis of breath can be used to discriminate between patients that are suspected of ventilator-associated pneumonia (VAP) who have positive cultures and who have negative cultures with high sensitivity (which could limit antibiotic…

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

## Samenvatting

### ID

NL-OMON20773

**Bron**
Nationaal Trial Register

**Verkorte titel**
BreathDx

**Aandoening**

Breath analysis; Ventilator-associated pneumonia (VAP)

### Ondersteuning

**Primaire sponsor:** Academic Medical Centre, Amsterdam, the Netherlands; and University Hospital South Manchester NHS Foundation Trust, United Kingdom
**Overige ondersteuning:** European Union; Marie Curie Actions: FP7 IAPP

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Combination of volatile markers that gives an accurate discrimination between patients that are suspected of VAP who have positive cultures and who have negative cultures with a sensitivity of at least 99%.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Intensive Care Units (ICUs) treat and monitor critically ill or unstable patients who may be unable to breathe on their own and whose organs may not be working properly. Medical equipment supports organ function until the patient recovers. Mechanical ventilators ('life support machines') support breathing. While this technology works well, patients on mechanical ventilators can develop life-threatening lung infections (pneumonia) as a complication. Pneumonia is treated quickly and effectively with antibiotic drugs. However, because patients on ventilators are already ill, it is not possible to diagnose pneumonia quickly and accurately. Therefore many mechanically ventilated patients will also receive antibiotic treatments 'just in case' which means that antibiotics will be used unnecessarily. A consequence of antibiotic overuse is that infecting bugs (microorganisms) become resistant so that it will be difficult to treat life- threatening pneumonia in the future. We need to develop new technologies to help decide quickly who has developed pneumonia during their time on mechanical ventilation. Recently, we have discovered that it is possible and safe to capture and measure breath chemicals of patients who are mechanically ventilated. The chemical profiles appear to distinguish patients acquiring dangerous lung microorganisms. This exciting finding implies that we could use these chemical patterns to determine quickly who is likely to require antibiotics and who does not. To progress this idea, we now wish to use our breath capture system in ICU ventilated patients suspected of developing pneumonia and, using analysis already developed in our laboratories, we will seek proof that these chemicals can distinguish between the presence and absence of pneumonia. At project completion we will be able to decide whether our innovation is ready for clinical testing across ICUs in Europe.

### Doel van het onderzoek

1) Molecular analysis of breath can be used to discriminate between patients that are suspected of ventilator-associated pneumonia (VAP) who have positive cultures and who have negative cultures with high sensitivity (which could limit antibiotic use).

2) Molecular analysis of breath can be used to specifically detect the causative pathogen in patients that are suspected of VAP (so that antibiotics can be targeted).

### Onderzoeksopzet

Only 1 time point: all samples are taken at time of recruitment.

**Onderzoeksproduct en/of interventie**

This is a diagnostic multicentre cross-sectional observational proof of concept study. Included patients will have been intubated and mechanically ventilated for at least 48 hours (based on the definition of VAP) and clinically suspected of having VAP. Exhaled air samples will be taken within 24 hours after the patient is suspected of VAP. Broncho-alveolar lavage fluid will be collected to clinically determine the presence of VAP.

# Contactpersonen

## Publiek

Philips Research

Tamara Nijssen
Eindhoven
The Netherlands

## Wetenschappelijk

Philips Research

Tamara Nijssen
Eindhoven
The Netherlands

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. 18 years and older

2. Intubated and mechanically ventilated for >48 hours

3. Suspected for ventilator associated pneumonia (VAP)

Definition of suspected VAP: start of antibiotics for a suspected lower respiratory infection in a patient that has been on mechanical ventilation for more than 48h

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients receiving end of life care

2. Patients where there is clinical suspicion of highly infectious disease (patients in strict isolation such as Middle East Respiratory Syndrome, Ebola or resistant tuberculosis)

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders |

**Controle:** N.v.t. / onbekend

### Deelname

Nederland

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|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-06-2015 |
| Aantal proefpersonen: | 153 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Positief advies

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|---|---|
| Datum: | 28-10-2016 |
| 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 | NL5933 |
| NTR-old | NTR6114 |
| Ander register | 19086 : UKCRN ID |

# Resultaten