# Exhaled breath analysis to diagnose acute lung injury.

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Octane concentrations in exhaled breath facilitate early detection of ARDS in ICU patients.

| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON27817

**Bron**
Nationaal Trial Register

**Verkorte titel**
DARTS study

**Aandoening**

ARDS, non-invasive diagnostic tests, early detection, octane

Dutch: ARDS, niet-invasieve diagnostische methoden, vroege detectie, octane

### Ondersteuning

**Primaire sponsor:** Amsterdam UMC, locatie AMC.
**Overige ondersteuning:** Longfonds, Health Holland

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Exhaled breath concentration of octane, measure by compact gas-chromatography.

# Toelichting onderzoek

### Achtergrond van het onderzoek

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. The diagnosis is based on timing, chest-radiography, origin of edema and the oxygenation values. However, still in half of the cases the diagnosis was missed. (ref) Gas-chromatography mass-spectrometry (GC-MS) is used in exhaled breath analysis to obtain concentrations of volatile compounds (VOCs). A biomarker that was found to be associated with ARDS is octane. Since GC-MS is labour intensive, requires specialized personnel and is not available bedside, it is not suitable for use in the intensive care unit (ICU) setting. Therefore a smaller device was developed which can quantitatively measure octane in exhaled breath. This point of care prototype will be tested in clinical setting and will be compared with other non-invasive diagnostic tests. Goal of this study is (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.

### Doel van het onderzoek

Octane concentrations in exhaled breath facilitate early detection of ARDS in ICU patients.

### Onderzoeksopzet

Within 48 hours after intubation untill a follow up of 90 days.
First measurement within 48 hours after intubation, second 24 hours later.

### Onderzoeksproduct en/of interventie

NA

# Contactpersonen

## Publiek

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### Wetenschappelijk

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## Deelname eisen

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

Intubated and mechanically ventilated for less than 48 hours.

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

• Patient is expected to be deceased within 24 hours.

• Exhaled breath collection deemed inappropriate by the attending physicians.

• Active withdrawal from the study by the patient or his/her legal representative.

• Present admission to the ICU is a readmission.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |

| | |
|---|---|
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-01-2019 |
| Aantal proefpersonen: | 500 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

## 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 | NL7170 |
| NTR-old | NTR7393 |
| Ander register | : NA |

## Resultaten