# Personalized Mechanical Ventilation Guided by UltraSound in Patients with Acute Respiratory Distress Syndrome

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Comparing different ventilation strategies in focal and non-focal ARDS in invasively ventilated patients admitted to the intensive care unit.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Lower respiratory tract disorders (excl obstruction and infection) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON51558

**Source**
ToetsingOnline

**Brief title**
PEGASUS

### Condition

- Lower respiratory tract disorders (excl obstruction and infection)

**Synonym**
Acute respiratory distress syndrome

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** ARDS, Lungmorphology, Personalized ventilation, Ultrasound

## Outcome measures

### Primary outcome

Mortality at day 90 (day of ARDS diagnosis considered as day 0).

### Secondary outcome

Secondary outcomes are mortality at 30 days, ventilator free days (VFD) at day

28, ICU length of stay, ICU mortality, hospital length of stay, hospital

mortality, complications as a result of ventilation.

# Study description

### Background summary

Acute respiratory distress syndrome (ARDS) is a severe lung disease with a 30% mortality rate that affects one in four ventilated patients in the intensive care unit. Personalized ventilation based on lung morphology in this patient population has the potential to reduce mortality. The LIVE study recently showed that application of personalized ventilation in practice is limited by a high interobserver variability in the determination of the type of lung morphology. This variability is caused by poor assessment of chest X-rays and the complex assessment and low availability of computed tomography (CT) scans. Correct determination of lung morphology is essential because incorrect ventilation strategies leads to a significant increase in mortality. Recently, our research group has developed a lung ultrasound method that can accurately determine lung morphology on the basis of a decision tree compared to CT scans. With the help of this study it will become clear whether personalized ventilation based on lung morphology, using lung ultrasound, will lead to a decrease in mortality in invasively ventilated patients with ARDS.

### Study objective

Comparing different ventilation strategies in focal and non-focal ARDS in invasively ventilated patients admitted to the intensive care unit.

### Study design

A multicenter randomized controlled trial.

### Intervention

Within 24 hours of inclusion, patients undergo a long ultrasound to distinguish between focal and non-focal ARDS. After differentiation, patients are randomized into the personalized ventilation group or the control group. Ventilation strategies per group will be as follows:

Personalized ventilation focal ARDS:
- Tidal volume: 6-8 ml/kg PBW
- PEEP: <10 cmH2O
- Mandatory prone position

Personalized Ventilation Non-focal ARDS:
- Tidal volume: 4-6 ml/kg PBW
- PEEP: >15 cmH2O
- Mandatory recruitment manoeuvres.

Control group ventilation strategy:
- Tidal volume: 6 ml/kg PBW
- PEEP: According to the PEEP/FiO2 table of the ALVEOLI study, with a maximum peak pressure below 30 cmH2O
- Prone position is encouraged

Except for different ventilation strategies, other aspects of treatment will be the same for all groups.

### Study burden and risks

We do not expect a difference in risk and burden between the different ventilation strategies and the use of lung ultrasound, as these techniques are already used in standard care of invasively ventilated patients with ARDS. Collecting demographics, ventilation parameters and outcome measures does not harm the patient

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

Admitted to a participating ICU, invasively ventilated, fulfil the Berlin criteria for moderate or severe ARDS.

## Exclusion criteria

Age under 18, pregnant, participation in an other interventional studie, conditions in which lung ultrasound is not feasible (e.g. subcutaneous emphysema, morbid obesity or wounds), mechanical ventilation for longer than 7 consecutive days in the past 30 days, history of ARDS in the previous month, body-mass index higher than 40 kg/m², intracranial hypertension, broncho-pleural fistula, chronic respiratory diseases requiring long-term oxygen therapy or respiratory support, pulmonary fibrosis, patients who are moribund or facing end of life and no informed consent.

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Treatment

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 09-08-2022 |
| Enrollment: | 100 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 04-07-2022 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 09-12-2022 |
| Application type: | Amendment |
| Review commission: | MEC Academisch Medisch Centrum (Amsterdam)<br><br>Kamer G4-214<br><br>Postbus 22660<br><br>1100 DD Amsterdam<br><br>020 566 7389<br><br>mecamc@amsterdamumc.nl |

# 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 |
| --- | --- |
| CCMO | NL79110.018.21 |