# Careful Ventilation in ARDS - The Caviards Trial

Published: 20-11-2024
Last updated: 27-12-2024

Reduce the risks associated with mechanical ventilation

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Respiratory tract infections |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON57112

**Source**
ToetsingOnline

**Brief title**
Caviards

### Condition

- Respiratory tract infections

**Synonym**
lung protection

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Unity Health Toronto - St Michael's Hospital
**Source(s) of monetary or material Support:** hoofdonderzoeker Toronto

### Intervention

**Keyword:** ARDS, Intensive Care, ventilation

## Outcome measures

### Primary outcome

mortality day 60

### Secondary outcome

duration of ventilation

ICU and hospital mortality

# Study description

### Background summary

ARDS is a major public heath problem. Treatment is challenging because there is no treatment for the lung leak. Individualizing Ventilator settings maybe could improve the adequacy of the ventilator.

### Study objective

Reduce the risks associated with mechanical ventilation

### Study design

randomized clinical trial with adaptive design assessing the efficacy of setting the ventilator based on measurements of respiratory mechanics (recruitability and effort) to reduce Day 60 mortality.

### Intervention

Ventilator settings on individual base

### Study burden and risks

no burden and risks

# Contacts

### Public

Unity Health Toronto - St Michael's Hospital

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CA
**Scientific**
Unity Health Toronto - St Michael's Hospital

36 Queen St E, Toronto 36
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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

age > 18
moderate or severe ARDS
admission Intensive Care

## Exclusion criteria

received mechanical ventilation > 7 days
known or suspected elevated intracranial pressure
known pregnancy

# Study design

### Design

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

**Primary purpose:** Treatment

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-12-2023 |
| Enrollment: | 45 |
| Type: | Anticipated |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 20-11-2024 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

## 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 |
| --- | --- |
| ClinicalTrials.gov | NCT03963622 |
| CCMO | NL84349.100.23 |