

# Real-time Pressure volume Loop monitoring as a guide for enhanced Understanding of changes in elemental cardiovascular physiology during Therapeutic strategies aiming for hemodynamic Optimization. Cohort I: Veno-arterial extracorporeal membrane oxygenation.

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Primary objective of this study is to enhance insight in differences in elemental cardiovascular physiology between different levels of VA-ECMO support, by comparing pressure-volume loop derived parameters between 4.0-3.0-2.0-1.0-0.5 L/min...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON51884

### Source

ToetsingOnline

### Brief title

PLUTO-I

### Condition

- Other condition
- Heart failures

**Synonym**

Combined refractory respiratory and hemodynamic failure, organ failure

**Health condition**

multi-orgaanfalen

**Research involving**

Human

**Sponsors and support**

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Ministerie van OC&W

**Intervention**

**Keyword:** Mechanoenergetics, Physiology, Pressure-volume loop, VA-ECMO

**Outcome measures****Primary outcome**

Primary study endpoints are the biventricular pressure volume loop characteristics reflecting cardiac mechanoenergetics, including stroke work and potential energy (together extrapolated into the pressure volume area) compared between 4.0-3.0-2.0-1.0-0.5 L/min VA-ECMO blood flow in individual patients.

Regarding the substudy: The difference in LV preload in individual VA-ECMO patients, reflected by the LV PVL derived parameter End-Diastolic Volume (EDV in mL). this parameter will be measured at 100% VA-ECMO blood flow for each PEEP level (i.e. 20, 10 and 0 cmH<sub>2</sub>O).

**Secondary outcome**

Secondary endpoints are differences in additional biventricular pressure-volume loop parameters between 4.0-3.0-2.0-1.0-0.5 L/min extracorporeal VA-ECMO blood

flow, including stroke volume, (forward and power) cardiac output, preload recruitable stroke work, tau, intraventricular dyssynchrony (both systolic and diastolic), dP/dt (maximal and minimal), effective arterial elastance and end-systolic elastance (the ratio between both reflecting ventricular-arterial coupling), the ventricular stiffness constant  $\beta$ , end-diastolic volume, end-diastolic pressure (including the end-diastolic pressure volume relation, EDPVR, trendline) as well as end-systolic volume, end-systolic pressure (including the end-systolic pressure volume relation, ESPVR, trendline), Starling Contractile index, stroke work to pressure volume area ratio as well as the ventricular volume on 0, 15, 30 and 100 mmHg ventricular pressure.

## Study description

### Background summary

Using VA-ECMO support, physiological stability can be maintained in patients with refractory hemodynamic failure as bridge to recovery, definitive therapy or decision making. Previous animal studies and computer simulations hypothesize increased left ventricular afterload as well as right ventricular distention during VA-ECMO and decision making concerning VA-ECMO weaning is largely based on bedside hemodynamic (including echocardiographic) parameters. Profound details of the effects of VA-ECMO on elemental cardiac physiology, including myocardial metabolic efficiency, are limited. We hypothesize biventricular pressure-volume loop measurement will enhance understanding of elemental cardiovascular physiology during different levels of VA-ECMO support. Besides, pressure-volume loop measurement will hypothetically provide opportunities in discovering novel predictors for successful weaning from VA-ECMO support.

A substudy will be added to the protocol investigating the interaction between PEEP and LV end-diastolic volume.

### Study objective

Primary objective of this study is to enhance insight in differences in

elemental cardiovascular physiology between different levels of VA-ECMO support, by comparing pressure-volume loop derived parameters between 4.0-3.0-2.0-1.0-0.5 L/min extracorporeal VA-ECMO blood flow. The secondary objective is to distinguish patients who will be successfully weaned from VA-ECMO versus patients who will fail to be weaned from VA-ECMO, based on pressure-volume loop derived parameters during the VA-ECMO \*weaning trial\* (on 0.5L/min extracorporeal blood flow).

## **Study design**

Single-centre clinical observational study with invasive measurements.

## **Study burden and risks**

The study is group-related: study questions could not be answered without participation of subjects belonging to the group in question. The expected burden for the enrolled subject is considered moderate, e.g. given the necessity for transporting an ICU patient on VA-ECMO support from ICU to the department of Interventional Cardiology. The potential risks are also considered moderate and comparable to diagnostic heart catheterization without the necessity of additional vascular puncture. Enrolled patients do not benefit from study participation, neither will individual study results (or pressure volume loop data obtained during study enrolment) influence the individual (ICU-) treatment strategy.

Potential complications of the alveolar recruitment (e.g. barotrauma and hemodynamic instability) are considered negligible as the safe airway pressure threshold (defined as Peak Pressure < 40 cmH<sub>2</sub>O) will be safeguarded continuously during the study measurement.

## **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**

On VA-ECMO support for any indication. According to our centre's protocol, indications for VA-ECMO initiation are hemodynamic and/or respiratory failure, cardiogenic shock, (accidental) hypothermia, ECPR, bridge to cardiac assist device implant and bridge to heart (and/or lung) transplant.

In short, all patients on VA-ECMO support are eligible for study participation, irrespective of their clinical indication for VA-ECMO initiation. We foresee study results will not be influenced by patient selection, since study inclusion criteria do not comprise any clinical conditions.

### **Exclusion criteria**

- Age < 18 years.
- Re-initiation of VA-ECMO during the same ICU admission.

In conclusion, all patients with established VA-ECMO support are eligible for study participation: clinical grounds and conditions are irrelevant for study inclusion, given the study's objective of identifying changes in baseline physiology induced by VA-ECMO support.

## **Study design**

## Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

## Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 28-02-2023

Enrollment: 20

Type: Actual

## Medical products/devices used

Generic name: Pressure-Volume Loop Catheter

Registration: Yes - CE intended use

## Ethics review

Approved WMO

Date: 21-03-2022

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 22-05-2024

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 14-01-2025

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## 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	NL78360.078.21