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…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	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 cmH20).

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 β, 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 cmH20) 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