Effectiveness of local anticoagulation of the ECMO oxygenator during flow reduction trial in patients on V-A ECMO: a prospective observational cohort study

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In this prospective observational study, the effects of our anticoagulation strategy during flow reduction trials will be studied. The results may help in performing safe flow reduction trials of adequate length, to be able to better decide whether...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON54247

Source
ToetsingOnline

Brief title
Anticoagulation during flow reduction in V-A ECMO

Condition

- Heart failures

Synonym
Cardiogenic shock

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: Anticoagulation, Extracorporeal Membrane Oxygenation (ECMO), Veno-arterial ECMO

Outcome measures

Primary outcome

The main endpoint of the study is the increase in APTT in the ECMO circuit at

the end of a flow reduction trial compared to the start of the flow reduction

trial

Secondary outcome

- The increase in systemic APTT after a flow reduction trial.

- The increase in aXa and Inten CT- Heptem CT both in the ECMO circuit and

systemic at the end of a flow reduction trial compared to the start of the flow

reduction trial

Study description

Background summary

Veno-arterial extracorporeal membrane oxygenation (V-A ECMO) is a support modus for patients with severe cardiogenic shock to maintain systemic haemodynamics and oxygenation/ventilation. It is applied in patients with cardiogenic shock, i.e. after large myocardial infarction, after complicated open heart surgery, or to restore circulation in refractory cardiac arrest. The V-A ECMO system consists of a multi-hole venous cannula, connected to a pump achieving a flow of 4-5 l/min, which pumps the blood through a membrane where oxygenation and CO2 removal takes place, after which it is reinfused though an arterial cannula (usually a retrograde cannula in the femoral artery). An antegrade (smaller) leg cannula is in place to provide oxygenated blood to the leg, to prevent ischaemia due to (partial) occlusion of the femoral artery by the retrograde cannula. Patients are on intravenous heparin to prevent clot formation in the oxygenator and cannulas. To improve efficiency of heparin to prevent oxygenator

clot formation, in the Erasmus MC, heparin is given directly before the oxygenator.
ECMO is a temporary support measure, aiming to bridge the patient to cardiac recovery or long term mechanical support. It is important to decide as early as possible if the patient can be weaned from ECMO support, since ECMO puts patients at risk for serious complications (bleeding, CVA, vascular complications). The decision to remove the ECMO is based on improvement of organ function and the result of a flow reduction trial.
In this flow reduction trial, the ECMO flow is reduced in steps to minimal support (<1 l/min), while monitoring haemodynamic and echocardiographic parameters. However, with low flow, the risk of clot formation is increased and flow < 1l/min can therefore only can be maintained for a short period, hampering assessment of organ function in this very short period.
During low ECMO blood flow in a weaning trial, heparin administration is increased by a factor 2-3 by increasing the perfusor speed. As this higher heparin administration is only maintained for 30 min, we assume that systemic effects of this small extra amount of heparin are neglectable. However, since the heparin is connected straight to the oxygenator, and the flow through the oxygenator is reduced at the same time, the ratio of heparin to blood flow increases, thereby probably increasing locoregional anticoagulation in the oxygenator.

Study objective

In this prospective observational study, the effects of our anticoagulation strategy during flow reduction trials will be studied. The results may help in performing safe flow reduction trials of adequate length, to be able to better decide whether the ECMO can be removed safely in the individual patient. Furthermore, most hospitals do not infuse their heparin close to the oxygenator, so if our results indicate local intense anticoagulation without systemic effects, this of interest for the care for patients on V-A ECMO in general, especially for patients with a tendency for bleeding where systemic over-anticoagulation needs to be avoided.

Primary Objective:
The aim of this observational study is to evaluate the increase in APTT in the oxygenator at the end of a flow reduction trial when heparin infusion rate has been increased during the trial.

Secondary Objective(s):
The secondary aim is to evaluate the change in systemic APTT, and the change in aXa and Intem CT- Heptem CT (ROTEM) systemically and in the oxygenator after a flow reduction trial when heparin infusion has been increased during the trial.

Study design

This is a prospective observational cohort study. In the Erasmus MC, the above described procedure of connecting heparin to the oxygenator is standardized per local protocol. As well, increasing the speed of heparin infusion during a flow reduction trial is routine care.
Flow reduction trials will be performed when indicated according to hospital protocol, i.e. as soon as organ function has stabilized and improvement in cardiac function has been noted.
Before starting the flow reduction trial, blood samples will be taken from the arterial line and ECMO circuit for the above mentioned coagulation parameters. After this the heparin infusion rate will be doubled/tripled and the flow-reduction trial will be performed. At the end of the flow reduction trial the blood test will be repeated (and ECMO flow and heparin dose will be set back to baseline values)
In the first 8 patients the heparin infusion rate will be doubles. If indeed there is no/limited change in APTT (<10s increase), the heparin infusion rate will be tripled in the consecutive 8 patients.

Study burden and risks

The burden and risk for the patient is minimal, since normal care will be delivered, including standardised flow reduction trials. The only study related procedures are obtaining blood samples,using acces points that are already in place in this patient category.
There is no benefit for the individual patient, there is potential benefit for patients supported in V-A ECMO, since performing this study adds on our knowledge of safely performing flow reduction trials.

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

All adult (>18 years old) patients on V-A ECMO with a planned flow reduction trial can be included in this study.

Exclusion criteria

- Patients in whom a heparin bolus has be given due to low APTT just prior to a planned flow reduction trial
- Patient with supratherapeutic APTT (>80ms)
- Flow reduction trial lasting less than 15 min
- No informed consent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-02-2024
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO Date:	07-12-2023
Application type:	First submission
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	NL77337.078.23