Transfusion Requirements and Mortality during Extracorporeal Membrane Oxygenation

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24666

Source
Nationaal Trial Register

Brief title
TREC

Health condition

ECMO is indicated in case of potentially reversible cardio(respiratory) failure refractory to conventional therapies. It can be divided in two main groups: the respiratory indications (e.g. acute respiratory distress syndrome), for which veno-venous ECMO is indicated; and isolated cardiac or combined cardiorespiratory failure (e.g. acute myocardial infarction), for which veno-arterial ECMO is indicated. It is a vulnerable population in the ICU, for which ECMO often functions as a “last resort” therapy.

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

The primary outcome is the total and daily amount of transfusion of blood products (red blood cells, platelets, plasma) and tranexamic acid, fibrinogen and prothrombin complex concentrate, received by patients on ECMO up to 28 days of support. Furthermore, clinical variables that may be associated with the occurrence of transfusion and a higher amount of transfusions will be evaluated.

Secondary outcome

Secondary outcomes are the 28-day mortality (calculated as from ECMO initiation) and complication rate (hemorrhage, thrombosis, infection, acute kidney injury).

Study description

Background summary

Extracorporeal life support (ECLS), also referred to as extracorporeal membrane oxygenation (ECMO), is used as a supportive method in case of temporary and potentially reversible cardio(respiratory) failure refractory to conventional therapies. Currently, for patients on ECMO, thresholds for transfusion of red blood cells, platelets, plasma and coagulating agents such as fibrinogen are only based on expert opinion. Several single-center retrospective studies show that many patients on ECMO receive many transfusions. However, these studies are based on a single-center and have small sample sizes. The aim of this study is to give an overview in patients on ECMO of the amount of transfusion of blood products (red blood cells, plasma and platelets) and administration of fibrinogen, tranexamic acid and prothrombin complex concentrate.

Study objective

We hypothesize that variance in transfusion practice for patients on ECMO is high.

Study design

N/A

Contacts

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Eligibility criteria

Inclusion criteria

Patients were included in the study if:
- They were admitted to the Intensive Care Unit (ICU) between January 1st 2018 up to July 1st 2019; AND
- They received support from extracorporeal membrane oxygenation (ECMO) during their ICU admission; AND
- They were aged 18 years and older.

Exclusion criteria

Patients were excluded in the study if:
- The total duration of ECMO support was less than 24 hours.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2019
Enrollment:	600
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	26-02-2020
Application type:	First submission

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
NTR-new	NL8413
Other	METC AMC : W19_222 # 19.267

Study results