Transfusion Requirements and Mortality during Extracorporeal Membrane Oxygenation

Gepubliceerd: 26-02-2020 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24666

Bron
Nationaal Trial Register

Verkorte titel
TREC

Aandoening

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.

Ondersteuning

Primaire sponsor: N/A
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Contactpersonen

Publiek

Amsterdam UMC, location AMC
Alexander Vlaar

+31205669111

Wetenschappelijk

Amsterdam UMC, location AMC
Alexander Vlaar

+31205669111

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-08-2019
Aantal proefpersonen:	600
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	26-02-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8413
Ander register	METC AMC : W19_222 # 19.267

Resultaten