Het beloop van bloedeigenschappen tijdens ECLS

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The use of ECLS can lead to systemic inflammatory response. It is likely that ECLS affects red blood cell and platelet function after its initiation, the time course of these changes and their clinical relevance is yet unclear.

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

Samenvatting

ID

NL-OMON29222

Bron
NTR

Verkorte titel
RBC ECLS

Aandoening

ECLS, ECMO, adults, coagulation

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: University Medical Center Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Red blood cell aggregation and elongation (deformability) assessed by a laser assisted optical rotational cell analyzer (LORCA) on days 1-3, and within 24 hours after weaning of ECLS

Toelichting onderzoek

Achtergrond van het onderzoek

Extracorporeal life support (ECLS) is increasingly used in the intensive care unit (ICU) and has resulted in improved survival of patients with critical respiratory or circulatory failure. However the incidence of hemorrhage (15-20%) and to a lesser extent thromboembolic events (2-4%) during an ECLS treatment are significant.

It is know that during ECLS hemolysis occurs and that platelet function may be affected. Although marked hemolysis in adult patients treated with venovenous ECLS is rare, hemolysis as an expression of membrane instability may be preceded by changes in aggregation and deformability of the red blood cells. Such changes may also affect the ability of red blood cells to interact in normal coagulation and thus result in hemorrhage. Intravascular hemolysis may also lead to organ injury through the effects of nitric oxide depletion and platelet activation. Recently it was found that free hemoglobin appeared to promote platelet adhesion and formation of micro thrombi on Von Willebrand factor, indicating that free hemoglobin is associated with thrombotic events.

Platelet dysfunction during ECLS can also be caused by factors other than hemolysis. For example a reduction in platelet aggregation was found after the initiation of ECLS and after 3 hours, although these findings could not be reproduced in a laboratory set-up using porcine blood. The interaction between platelets and leucocytes induces leucocytes to secrete pro-inflammatory cytokines and monocytes to express tissue factor. In a small study in critically ill neonates, it was shown that these processes are time-dependent with a progressive increase in activity leading to thrombocytopenia and decreased platelet aggregation in absence of endothelial activation. The type of underlying illness with systemic inflammatory response might lead to differences in the changes in the red blood cell properties and platelet function. As was shown in a prospective study in patients with and without sepsis. RBC deformability was already reduced in septic patients at ICU admission, and worsened in non-survivors. In non-septic patients these changes were not observed.

Thus, although it is likely that ECLS affects red blood cell and platelet function after its initiation, the time course of these changes and their clinical relevance is yet unclear.

Doel van het onderzoek

The use of ECLS can lead to systemic inflammatory response. It is likely that ECLS affects red blood cell and platelet function after its initiation, the time course of these changes and their clinical relevance is yet unclear.

Onderzoeksopzet

Before start, days 1-3, 5, 7, 10, 14, 21 (when appropriate) and within 24 hours after weaning of ECLS

Onderzoeksproduct en/of interventie

Collecting data about coagulation tests during ECLS, including conventional tests such as APTT, PT, platelets, D-dimer, free Hb and alternative tests, including LORCA and Multiplate

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All adult patients who start with ECLS in the ICU (according to the guidelines, ECLS can be considered in acute severe heart or lung failure with high mortality risk despite optimal conventional therapy).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Pregnancy

- Start of ECLS not in the ICU, e.g. after cardiothoracic surgery

- Use of ECLS only for high risk procedure like percutaneous cardiac intervention with planned removal of ECLS within 24 hours.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2018
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-05-2018
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	NL7035
NTR-old	NTR7240
Ander register	: RBC ECLS 2018

Resultaten