Monitoring van de stolling bij jonge ECMO patienten

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Addition of alternative tests (TEG/ROTEM® and/or TGA) which reflect the whole hemostatic status of a patient might help recognizing the level of thrombin formation and fibrinolysis and improve care in ECMO patients and potentially reduce the risk of...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20511

Bron
NTR

Verkorte titel
CHEKid-study

Aandoening

ECMO
Coagulation
Stolling
child
kind

Ondersteuning

Primaire sponsor: ErasmusMC Sophia Children's Hospital, Rotterdam
Overige ondersteuning: Vrienden van Sophia

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1.Bleeding complications in the first 14 days of ECMO therapy
2.Clotting complications in the first 14 days of ECMO therapy

Toelichting onderzoek

Achtergrond van het onderzoek

Bleeding and clotting complications occur in about 50% of the pediatric extracorporeal membrane oxygenation (ECMO) patients, causing a decrease in survival of about 40%.(1-3) The interaction between blood and the ECMO circuit generates a hypercoagulable state, and unfractionated heparin is used to maintain patency of the circuit as well as to reduce thrombotic events while minimizing bleedings. Worldwide, no consensus exists about how to monitor this precarious hemostatic balance.

Current conventional tests (APTT, ACT and anti-FXa assay) assess only isolated parts of the coagulation cascade, while alternative tests (thromboelastography [TEG/ROTEM] and thrombin generation assay [TGA]) assess the complete coagulation cascade. Therefore, we hypothese that the alternative coagulation tests better reflect the thrombotic or haemorrhagic phenotype than the conventional tests, and as a consequence will improve coagulation monitoring in ECMO patients, leading to less hemostatic complications and improved survival. In this pilot study we will prospectively investigate the ability of both conventional and alternative coagulation tests to predict bleeding and clotting complications in 160 ECMO children in 8 established ECMO centers worldwide. We expect to find one or a combination of coagulation tests with a good association with the bleeding and/or clotting complications. In a future project, the test(s) can be incorporated in a new anticoagulation protocol, that will be studied in a randomized controlled trial.

Doel van het onderzoek

Addition of alternative tests (TEG/ROTEM® and/or TGA) which reflect the whole hemostatic status of a patient might help recognizing the level of thrombin formation and fibrinolysis and improve care in ECMO patients and potentially reduce the risk of hemostatic complications.

Onderzoeksopzet

Before start of ECMO, the first 14 days of ECMO therapy and within 24 hrs after stop of ECMO.

Onderzoeksproduct en/of interventie

Collecting data about all coagulation tests during the first 14 days of ECMO, including conventional tests such as APTT, PT/INR, ACT, platelets, anti-Xa level, D-dimer, antithrombin and alternative tests, including ROTEM/TEG and TGA.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Children from 0 to 18 years old treated with ECMO therapy can be included in this study within 48 hours after start of ECMO and after obtained informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients without informed consent

2. Patients after 48 hours of start of ECMO

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:	01-02-2019
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL6977
NTR-old	NTR7165
Ander register	na : Project S18-33 (Vrienden van Sophia)

Resultaten