Monitoring van de stolling bij jonge ECMO patienten

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20511

Source
NTR

Brief title
CHEKid-study

Health condition

ECMO
Coagulation
Stolling
child
kind

Sponsors and support

Primary sponsor: ErasmusMC Sophia Children's Hospital, Rotterdam
Source(s) of monetary or material Support: Vrienden van Sophia

Intervention

Outcome measures

Primary outcome

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

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

Secondary outcome

None

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

1. Patients without informed consent

2. Patients after 48 hours of start of ECMO

Study design

Design

Study type: Observational non invasive

Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2019
Enrollment:	160
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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

Study results