Farmacokinetics and farmacodynamics of drugs used in neonates and children during Extracorporal Membanous Oxygenation (ECMO)

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The objective of the study is to karacterize Pharmacokinetics and pharmacodynamics of frequently and routinely used drugs in children and neonates undergoing ECMO treatment and ultimately to formulate dosing regimes for these drugs for patients...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON30690

Source
ToetsingOnline

Brief title
farmacotherapy during ECMO

Condition

- Other condition

Synonym
heart-lung machine

Health condition

patienten aan ECMO

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: child, ECMO, pharmacokinetics, pharmaodynamics

Outcome measures

Primary outcome

Karacterizing the Pharmacokinetics of different drugs (analgesia, sedatives, antibiotics, inotropic agents, PGE5 inhibitor, and diuretics) routinely used in patients undergoing ECMO.

Describing the relationship between pharmacokinetics and demografical, physiological, pathophysiological factors like diagnosis, genotype, PRISM/PIM scores, liver and kidney function

albumin concentrations, different ECMO modi, ECMO flow, dialysis, bloodtransfusions and ventilator settings.

Secondary outcome

Karacterizing the relationship between pharmacokinetics and clinical effects of the above mentioned medication.

Describing the relationship between pharmacodynamics and demografical, physiological, pathophysiological factors.

Formulating dosing regimes for the studied medication for patients treated with ECMO.

Study description

Background summary

Children treated with ECMO recieve a wide variety of medication. There is only sparse data available on farmacokinetics and farmacodynamics of these drugs during ECMO. Dosing regimens are empiric or are extrapolated from data gathered from children and adult population not on ECMO.

Study objective

The objective of the study is to karacterize Pharmacokinetics and pharmacodynamics of frequently and routinely used drugs in children and neonates undergoing ECMO treatment and ultimately to formulate dosing regimes for these drugs for patients undergoing ECMO treatment.

Study design

Prospective observational study. Medication will be administered following local protocol and routine.

Study burden and risks

Patients recieve standard intensive care treatment and monitoring following local clinical routine and protocols. Standardized bloodsamples for bloodgas analysis, bloodcount, electrolytes, liver and kidney functiontests, and coagulation will be preformed following normal protocol.
For this study extra bloodsamples will be drawn from the ECMO circuit or an indwelling arterial catheter, to measure drug concentrations. On the first day during ECMO a maximum amount of 18ml of blood will be drawn. On the following days 6-9ml per 24 hours will drawn. MOst neonates on ECMO have a bodyweight of 3kg. Total circulating bloodvolume is 80ml/kg which comes down to 240ml for a 3kg newborn. Our neonatal ECMO system is primed with 250ml blood. Total circulating bloodvolume of patient and ECMO system is 490ml. 18ml/day amounts to bloodwithdrawel of less than 5% of the total circulating bloodvolume of the patient and the ECMO system.
Urine samples from a trans urethral catheter and dialysis filtrate samples will be drawn every 8 hours to measure drugs and drug metabolites.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

neonates and children 0-18 year on ECMO

Exclusion criteria

Witheld informed consent

Study design

Design

Study phase:	4
Study type:	Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-02-2007
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	09-02-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL14729.078.06