The change of red blood cell properties and platelet function over time during extracorporeal life support

Published: 09-05-2018
Last updated: 12-04-2024

Objective: Primary objective: 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. Secondary objectives are red blood...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Red blood cell disorders
Study type	Observational non invasive

Summary

ID

NL-OMON46661

Source
ToetsingOnline

Brief title
RBC ECLS

Condition

- Red blood cell disorders

Synonym
red blood cell properties and platelet function

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cell aggregation, deformability, Extracorporeal life support, Intensive care unit

Outcome measures

Primary outcome

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.

Secondary outcome

Red blood cell aggregation and elongation (deformability) assessed by a LORCA on 5, 7, 10, 14, 21 (when appropriate) and within 24 hours after weaning of ECLS.

Platelet aggregation assessed by the multiple platelet function analyzer (Multiplate) on days 1, 2, 3, 5, 7, 10, 14, 21 (when appropriate) and within 24 hours after weaning of ECLS.

Von Willebrand-factor, free hemoglobin, reticulocytes, and D-dimers on days 1, 2, 3, 5, 7, 10, 14, 21 (when appropriate) and within 24 hours after weaning of ECLS.

Study description

Background summary

Rationale: Extracorporeal life support (ECLS) is increasingly used in the intensive care unit and has resulted in improved survival of patients with

critical respiratory or circulatory failure. However the incidence of hemorrhage and to a lesser extent thromboembolic events during an ECLS treatment are significant. Hemolysis as an expression of membrane instability may be preceded by changes in aggregation and deformability of the red blood cells. Platelet dysfunction can be caused by hemolysis but also due to changes in aggregation. Systemic inflammatory response might also play a roll. 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.

Study objective

Objective: Primary objective: 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. Secondary objectives are red blood cell aggregation and elongation (deformability) assessed by a LORCA on 5, 7, 10, 14, 21 (when appropriate) and platelet aggregation assessed by the multiple platelet function analyzer (Multiplate) and Von Willebrand-factor, free hemoglobin, reticulocytes and D-dimers on days 1, 2, 3, 5, 7, 10, 14, 21 (when appropriate) and within 24 hours after weaning of ECLS.

Study design

Observational cohort study

Study burden and risks

The risk and burden of an extra 5 ml blood on the study days taken from the arterial line is deemed in proportion to the potential value of the research. This study will not be beneficial for the subject. The risk of participation is considered negligible and the burden minimal because the arterial line is in place as part of standard care. Patients on ECLS are critically ill patients and therefore in the majority of the cases incapacitated due to critical illness and/or sedation.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL

Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All adult patients who start with ECLS in the ICU

Exclusion criteria

- 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.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2018
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	09-05-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL64227.042.17