Changing Hemodynamics during ECMO SupporT

Published: 29-06-2015
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To study the macro- and microcirculatory effects of VV-ECMO treatment.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON42041

Source
ToetsingOnline

Brief title
CHEST

Condition

- Respiratory tract therapeutic procedures

Synonym
ECMO, lung support.

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ECMO, Hemodynamics

Outcome measures

Primary outcome

Primary

1) TTE: Right ventricular function

Secondary outcome

Secondary

1) TTE: Left ventricular function

2) SDF: Proportion of perfused vessels (%)

3) Shunt fraction

Study description

Background summary

Veno-venous extra corporeal membrane oxygenation (VV-ECMO) is increasingly used to treat respiratory failure such as in patients with acute respiratory distress syndrome (ARDS). However the hemodynamic effects of VV-ECMO have only been described in neonatal patients and remain to be determined in adults.

Study objective

To study the macro- and microcirculatory effects of VV-ECMO treatment.

Study design

A pilot prospective observational cohort study. We will include patients who receive VV-ECMO during the period April 1st 2015 - April 1st 2018. Patients will be subjected to transthoracic echocardiogram (TTE) measurements before and directly after VV-ECMO initiation as well as 24 hours after ECMO initiation. Sidestream darkfield imaging (SDF) will be performed at the same time points as well as a venous blood gas.

Study burden and risks

Patients do not benefit from this study. The additional burden and risks for

patients participating is minimal. Venous blood gas measurements will be taken from an existing venous line. The hemodynamic measurements we will perform are non-invasive, not painful and are done while the patient is sedated, minimizing patient burden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients admitted to the intensive care receiving veno-venous ECMO treatement

Exclusion criteria

No exclusion criteria

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-05-2016
Enrollment:	61
Type:	Actual

Ethics review

Approved WMO Date:	29-06-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL51833.018.15