Evaluation of drainable volume measurements and their usage for predicting optimal cardiac support in patients supported by veno-arterial extracorporeal life support.

Published: 08-07-2014
Last updated: 21-04-2024

To assess drainable volume and cardiac recovery using standard recorded perfusion data in patients supported by VA-ELS.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON40651

Source
ToetsingOnline

Brief title
Evaluation VA-ELS

Condition

- Heart failures

Synonym
cardiac failure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cardiac failure, DFI, Drainable volume, VA-ELS

Outcome measures

Primary outcome

Changes in drainable volume and changes in cardiac function.

Secondary outcome

None.

Study description

Background summary

Veno-arterial extracorporeal life support (VA-ELS) is used to support patients with acute cardiac failure. In that context, sufficient drainable venous volume is crucial for reliable and adequate support. To date, no reliable measurement method exists to monitor drainable volume adequately. Furthermore, it is still unresolved how to diagnose adequate cardiac recovery.
Previous (pre)clinical studies showed that the calculation of the dynamic filling index may provide a valuable parameter to monitor the drainable volume in patients supported by VA-ELS. In addition, a case report showed that measurement of the dynamic filling index could successfully be used to estimate cardiac recovery in a single patient supported by VA-ELS in the ICU.

Study objective

To assess drainable volume and cardiac recovery using standard recorded perfusion data in patients supported by VA-ELS.

Study design

A prospective interventional study.

Intervention

Small variations in the pump speed of the VA-ELS pump.

Study burden and risks

The dynamic filling index (DFI) is calculated from standard recorded perfusion data during small variations (<5%) of the pump speed. The pump speed variations needed for the estimation of the DFI are relatively small compared to pump speed variations regularly used by perfusionists to respond to changes in the patients circulatory status, to obtain adequate venous drainage, and to train the heart during weaning. Moreover, the variations in pump speed needed to determine the DFI take less than 3 minutes, and are induced by a perfusionist who remains present at all times during the measurements. Should any unforeseen negative reaction occur, the measurement can be stopped immediately without further consequences. Thus, to the current knowledge the DFI measurements do not add to the risks already present during VA-ELS.

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

Supported by veno-arterial extracorporeal life support (VA-ELS)
Signed informed consent
>18 years

Exclusion criteria

Pregnancy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-09-2014
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	08-07-2014
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL49011.000.14