Percutaneous versus surgical VA ECMO insertion:
a pilot study to evaluate feasibility and safety

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Primary objectivesAs our primary efficacy objective, we will compare procedural success rate between the two groups, which is defined as defined as the successful insertion of both arterial and venous cannulas and subsequent initiation of ECMO-flow…

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

Summary

ID

NL-OMON53934

Source
ToetsingOnline

Brief title
Percutaneous versus surgical VA ECMO

Condition

- Heart failures

Synonym
acute heart failure, cardiogenic shock

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Percutaneous, Shock, Surgical, VA ECMO

Outcome measures

Primary outcome

Main study parameter/endpoint

Primary efficacy endpoint: procedure success rate, defined as the successful insertion of both arterial and venous cannulas within 3 attempts and subsequent successful initiation of ECMO-flow

Primary safety objective: is a composite of cannulation-associated adverse events during cannulation, during ECMO and after ECMO decannulation, including:

o Vascular complications, defined as development of a false aneurysm, dissection, perforation or another type of vascular damage

o Cannulation site bleeding and other major bleeding (BARC type 2 and above)

o The development of limb ischemia requiring fasciotomy or amputation

o Local infections, defined as a wound culture-proven infection

o Systemic infections, defined as blood culture-proven infection

Secondary outcome

Secondary study parameters/endpoints

Separate analysis of the components of the composite endpoint:

o Vascular complications, which is defined as the development of a false aneurysm, dissection, perforation or another type of vascular damage

o Cannulation site bleeding and other major bleeding (BARC type 2 and above)

o The development of limb ischemia requiring fasciotomy or amputation

o Local infections, defined as a wound culture-proven infection

o Systemic infections, defined as blood culture-proven infection

As well as:

- Thirty-day mortality

- Cross-over rate due to failed cannulation

- Procedure time, defined as time from first puncture/incision to the moment of

ECMO-flow initiation

- Number of attempts with successful puncture, but failure to advance the wire

- Number of failed percutaneous attempts, defined as wire insertion without

successful cannulation

Study description

Background summary

the traditional method for femoral cannulation in the setting of veno-arterial extracorporeal membrane oxygenation (VA ECMO) is a surgical approach. Techniques for percutaneous insertion have improved drastically over the recent years, and this less invasive procedure has been associated with a lower complication rate. Therefore, it has increasingly become first-line strategy in ECMO-centers worldwide.

Study objective

Primary objectives
As our primary efficacy objective, we will compare procedural success rate between the two groups, which is defined as defined as the successful insertion of both arterial and venous cannulas and subsequent initiation of ECMO-flow. A percutaneous approach is considered feasible when a first line success rate of 75% is reached. Our primary safety objective is the comparison of a composite of cannulation-associated adverse events, including vascular complications,

bleeding, limb ischemia and cannulation-site as well as systemic infection. A percutaneous approach is considered safe when the cannulation-associated adverse event rate is equal in both groups, or lower in the percutaneous group.

Secondary objectives
As our secondary efficacy objective, we will compare procedural characteristics, such as number of attempts (including the number of failed attempts), cross-over rates and procedure duration. Our secondary safety objective consists of the comparison of each individual component of the composite safety endpoint, as well as thirty-day mortality, between the two groups.

Study design

Two-center randomized controlled trial, open

Intervention

Percutaneous insertion of ECMO cannulas

Study burden and risks

Patients presenting with an indication for VA ECMO are critically ill and as such, have a dismal prognosis. As outlined above, a selected group of patients is eligible for this treatment modality to potentially improve outcomes.

For this study, these patients are randomized to either surgical implantation of VA ECMO (standard of care), or percutaneous implantation (intervention group). We expect complication rate in the intervention group to be similar or lower, when compared to standard of care.

This study concerns a critically ill patient population. As a percutaneous technique may be employed faster and as it may also be associated with a lower complication rate, the potential benefit for this patient population outweighs the known potential risks. Importantly, both surgical and percutaneous implantation methods are widely established, standard of care interventions. Risks associated with either procedure are deemed relatively low

Contacts

Public
Amsterdam UMC

Meibergdreef 9

Amsterdam 1105AZ
NL
Scientific
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Age above 18
2. Indication for VA ECMO support (according to international guidelines and as discussed in our multidisciplinary team)
3. (Deferred) informed consent by proxy

Exclusion criteria

Patients who are not suitable for undergoing VA ECMO support according to our standard of practice. In addition, patients undergoing central cannulation in the operating theatre, are excluded from participation, as well as patients with no peripheral vascular access

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2022
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-03-2023
Application type:	First submission
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	NL82403.018.22