PREVENTION OF VASOPLEGIA WITH THE USE OF CYTOSORB

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To test the efficacy and cost-effectiveness of using CytoSorb in preventing vasoplegia in patients with heart failure undergoing cardiac surgery on CPB.

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

Summary

ID

NL-OMON55069

Source
ToetsingOnline

Brief title
CytoSorb-HF Trial

Condition

- Heart failures
- Cardiac therapeutic procedures
- Decreased and nonspecific blood pressure disorders and shock

Synonym
Vasoplegia - Low blood pressure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cardiopulmonary Bypass, CytoSorb, Heart Failure, Vasoplegia

Outcome measures

Primary outcome

- Change in systemic vascular resistance index after phenylephrine

administration (delta SVRi) after CPB;

- Reduction in the occurrence of Vasoplegic Syndrome (VS).

Secondary outcome

Secondary study parameters:

- Delta SVRi in ICU;

- Total dose of vasopressors administered;

- Change in IL-6, IL-8, IL-10 levels;

- Change in sublingual microcirculation;

- Change in MAP after phenylephrine administration;

- Hours on mechanical ventilation;

- Hours on mechanical circulatory support;

- Hours on postoperative renal replacement therapy;

- End-organ damage (kidney dysfunction);

- Change in total Sequential Organ Failure Assessment Score (SOFA);

- Amount of used blood transfusion products;

- Amount of used resuscitation fluids;

- Length of Intensive Care Unit (ICU) stay;

- Length of the hospital stay;

- 30-Day hospital readmissions;

- All-cause mortality.

Cost effectiveness parameters:

- Total administered dosage of vasopressors;

- Amount of used blood transfusion products;

- Amount of used resuscitation fluids;

- Duration of surgery;

- Length of ICU stay;

- Length of the hospital stay;

- Hospital readmissions.

Study description

Background summary

The incidence and prevalence of chronic heart failure are increasing. Despite the expansion of therapeutic options, overall survival and quality-of-life remain poor. When optimal medical therapy and cardiological interventions have failed to improve a patient*s condition, surgical intervention may be a valid option in order to improve cardiac function. Different surgical treatments have improved clinical outcome. Unfortunately, heart failure surgery is associated with an increased risk on vasoplegia. This syndrome is characterized by hypotension and the continuous need of vasopressors, despite a normal or high cardiac index. The incidence of vasoplegia ranges from 11-31% in patients undergoing heart failure surgery. The prognosis of vasoplegia is poor. Prolonged hypotension and the accompanying hypoperfusion lead to end-organ dysfunction and is associated with an increased morbidity and mortality. We hypothesize that the balance of the vascular system of patients with heart failure is fragile and therefore could easily be disturbed by a systemic inflammatory response syndrome (SIRS) caused by the cardiopulmonary bypass (CPB) and surgical trauma, making these patients more prone to develop vasoplegia. Minimalizing this SIRS reaction could be a strategy to prevent vasoplegia.

Study objective

To test the efficacy and cost-effectiveness of using CytoSorb in preventing

vasoplegia in patients with heart failure undergoing cardiac surgery on CPB.

Study design

The proposed study is an investigator-initiated single-center randomized controlled clinical trial in patients with HF who will undergo cardiac surgery on CPB. In total 36 patients will be enrolled. Patients will be randomized to receive either CytoSorb treatment or standard of care without CytoSorb treatment in a 1:1 ratio. The study intervention protocol starts on the day of the surgery and ends 4 days postoperatively. CytoSorb treatment will be conducted intraoperatively in the operating room. Patients' clinical data is collected up to day 30 after heart surgery.

Intervention

The investigational treatment that the patients randomized for CytoSorb treatment will receive includes the use of the CytoSorb device in the CPB circuit .

Study burden and risks

The treatment protocol follows the standard of care procedure except for the CytoSorb application in the CPB circuit in the intervention group and phenylephrine challenges, 5x2 blood samples (10 ml each, 100ml total) and sublingual microcirculation monitoring in both study groups. The CytoSorb device has been proven to be safe, feasible and well-tolerated during cardiac surgeries and no major risks or side-effects have been reported. In rare cases, a hypersensitivity reaction may occur during CPB, however no case has been reported until now. In addition, CytoSorb is capable of removing drugs (i.e. antibiotics, pressor agents, etc.). Therefore, the physician is advised to measure concomitant drug concentrations when CytoSorb treatment is used if a test is available and adjust the drug dosage accordingly. None of the drugs used in the anaesthetics protocol is known to be adsorbed by CytoSorb. Patients included in the intervention group may benefit from the intervention, since we are expecting a better outcome with regards to the occurrence of vasoplegia. Patients in the control group will not experience a direct benefit from participating in the study. However, generation of comparative data on the use of CytoSorb might help discover preventive options for vasoplegia, leading to safer surgical interventions and improved outcome. The measurements necessary to assess the defined study parameters are not expected to negatively influence the result of treatment.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

-Diagnosed with heart failure (HF) in line with the European Society of Cardiology (ESC)
guidelines
-Left ventricular ejection fraction (EF) <=35%
-Undergoing cardiac surgery on cardiopulmonary bypass (CPB) with an anticipated duration of at least 120 minutes
-Age >= 18 years.

Exclusion criteria

-Incapacitated
-Emergency operation

-Need for moderate or high dosages of intravenous inotropic support (>4 gamma dobutamine or dopamine) and/or vasopression;
-Severe tricuspid regurgitation;
-Daily use of nitroglycerine or isosorbide dinitrate
-Use of alpha blockers
-Being Heparin Induced Thrombocytopenia (HIT) positive and citrate regional* anticoagulation is unavailable as an alternative anticoagulation method
-Platelet count < 20,000/µL.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-10-2021
Enrollment:	36
Type:	Actual

Medical products/devices used

Generic name:	CytoSorb
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	27-11-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

	metc-ldd@lumc.nl
Approved WMO Date:	09-07-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	13-08-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
ClinicalTrials.gov	NCT04812717
CCMO	NL71623.058.20