Cytokine adsorption for vasoplegic syndrome after cardiothoracic surgery

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We aim to investigate the clinical benefit of cytokine adsorption on post-cardiothoracic surgery vasoplegic syndrome.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Decreased and nonspecific blood pressure disorders and shock
Study type	Interventional

Summary

ID

NL-OMON55605

Source
ToetsingOnline

Brief title
CYTATION

Condition

- Decreased and nonspecific blood pressure disorders and shock

Synonym
paralysis of the blood vessels, Vasoplegia

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: CytoSorbents, Inc.,Cytosorbents;Inc.

Intervention

Keyword: Cardiothoracic surgery, Cytokine adsorption, Vasoplegic syndrome

Outcome measures

Primary outcome

Cumulative vasopressor need and total amount of fluid administration.

Secondary outcome

Time to hemodynamic stabilization, ICU length of stay, hospital length of stay,

mortality, incidence of acute kidney injury and need for renal replacement

treatment.

Study description

Background summary

Vasoplegic syndrome is a frequently occurring complication after cardiac surgery and is associated with increased mortality and morbidity. It is attributed to excessive inflammation occurring as a consequence of the sternotomy wound itself and of the cardiopulmonary bypass. Clinical observations and case series have shown a beneficial effect of cytokine adsorption on mortality, vasopressor need and hemodynamic stabilization in both septic patients and after cardiac surgery, however prospective data is lacking.

Study objective

We aim to investigate the clinical benefit of cytokine adsorption on post-cardiothoracic surgery vasoplegic syndrome.

Study design

Randomised controlled trial.

Intervention

Treatment with cytokine adsorption in addition to standard treatment.

Study burden and risks

Vasoplegic syndrome is a known and severe complication of cardiothoracic surgery. Patients are given supportive treatment; adjunctive treatment with

cytokine adsorption may help decrease vasopressor need and increase hemodynamic stabilization. Patients in the interventional arm will receive hemoadsorption via a central catheter placed in the femoral vein. The most common complication of placing a catheter in the femoral vein is hematoma formation. This complication is rare and usually self-limiting. More severe catheter related problems such as infection and thrombosis are not to be expected since the catheter will be removed (after 24h) before these complications typically occur. A dialysis filter will be placed downstream of the cytokine filter, monitoring of calcium chelation will be performed according to the local standard citrate anticoagulation protocol. Patient survival is registered for 30 days after ICU discharge. After ICU discharge there are no additional burdens associated with participation.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. >= 18 year
2. Post elective cardiac surgery
3. Vasoplegic syndrome occurring within 12 hours after surgery, defined as:
a. High vasopressor dose (norepinephrin > 0.25 mcg/kg/min) needed for adequate MAP (> 65 mmHg) despite adequate crystalloid fluid resuscitation (> 30 ml/kg IBW), persisting more than one hour.
b. Echocardiographic evidence of adequate cardiac output, defined as cardiac index > 2,5L/min/m2. Stroke volume is calculated as the product of Aortic velocity time integral and left ventricular outflow tract diameter. Cardiac output is calculated by multiplying stroke volume with heart rate. This is then divided by body surface area to obtain cardiac index. , c. IF; a pulmonary artery catheter was already inserted perioperatively:
- Cardiac index > 2,5l/min/m2 AND low systemic vascular resistance (SVRI < 1600 dynes/sec/cm5/m2 , SVR < 800 dynes/sec/cm5)
- OR; normalized vascular resistance at due to high-dose vasopressor use (norepinephrin > 0.25 mcg/kg/min).

Exclusion criteria

- Severe coagulopathy resulting in hemodynamic instability
- Significant bleeding defined as 400 ml/1st hour, 200 ml/ 2nd hour, 100 ml/h; necessitating rethoractomy or transfusion
- Severe thrombocytopenia (< 80)
- Cardiac tamponade
- Active infectious disease (non-profylactic antibiotics)
- Active inflammatory disorders or chronic use of immunosuppressive medication
- Need for extracorporeal life support system
- Severe renal dysfunction pre-operation (GFR <30) or prior kidney transplant
- Contra-indications for PiCCO: Atrial or ventricular arrhythmia at time of inclusion, Intra-Aortic Balloon pump, Aortic aneurysm, Pneumonectomy, Pulmonary embolism, Intracardiac shunt
- Allergy for: polystyrene/divinylbenzene, polycarbonate, polypropylene, silicone and polyester
- Acute liver failure with blood transaminases values >1000 IU/L
- Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-07-2019
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	CytoSorb® 300 mL Device
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	28-11-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL65440.068.18
Other	nog niet toegekend