Vascular reactivity in patients with heart failure

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22119

Source
NTR

Brief title
VASOR

Health condition

Heart failure

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Leiden University Medical Center

Intervention

Outcome measures

Primary outcome

- Change in SVR after phenylephrine administration

Secondary outcome

In vivo

- Change in mean arterial pressure (MAP) after phenylephrine administration.

- Change in MAP, SVR and CI after nitroglycerin administration.

- Vasoplegia

- Copeptin, norepinephrine, epinephrine, atrial natriuretic peptide (ANP), brain natriuretic peptide (BNP), N-terminal prohormone of BNP (NTproBNP), angiotensin II, cortisol, aldosterone, renin and vanillylmandelic acid (VMA) levels

Ex vivo

- Change in vessel diameter in response to vasoactive drugs.

- Activated signalling proteins which are associated with vasoresponsiveness.

- Receptors (quantity and function) which are associated with vasoresponsiveness.

Study description

Background summary

Vasoplegia is a state defined by hypotension, a high cardiac index and the continuous need of vasopressors. It occurs in 5-25% of the patients undergoing cardiac surgery on cardiopulmonary bypass (CPB) and is associated with an increased morbidity and mortality. Vasoplegia is a result of activation of several vasodilator pathways, inactivation of vasoconstrictor pathways and the resistance to vasopressors, but the precise aetiology remains unclear. Important risk factors for the development of vasoplegia after cardiac surgery are a left ventricular ejection fraction <30%, CPB and CPB duration.

Study objective

We hypothesize that in patients with chronic heart failure, the responsiveness of the vascular system is
permanently altered due to chronic endogenous adrenergic stimulation, resulting in down regulation and/or
desensitization of vascular a1-adrenoreceptors. The vascular system of patients with heart failure is easily pushed out
of balance by the systemic inflammatory reaction caused by the CPB and surgical trauma, making these patients more
prone for developing vasoplegia. Also activation of inducible nitric oxide synthase, activation of adenosine triphosphate
dependent potassium channels and deficiency of arginine vasopressin may play an important

role.

Study design

The phenylephrine challenge will be performed:

1. Before induction, before start medication (dobutamine, milrinone, noradrenalin)

2. Before induction, after start medication

3. After induction

4. After CPB, before emergence

5. On day 1 postoperative

The vasodilation test will be performed at the beginning of the surgery after placement of the arterial catheter and 1 day post-operatively.

The biopsy (pericardial fat) will be collected at the beginning of the surgery and at from the same area as the surgical incision.

In phase 2 of the study (VASOR part 2) only a biopsy will be collected.

Intervention

- Phenylephrine challenge

- Vasodilation test;
- Pericardial fat biopsy.

Contacts

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Eligibility criteria

Inclusion criteria

Group 1:

- Diagnosed with heart failure in line with the European Society of Cardiology (ESC) guidelines (McMurray et al., 2012);

- LVEF <35%.

- Undergoing cardiac surgery on CPB.

Group 2:

- Not diagnosed with heart failure;

- LVEF >50%.

- Undergoing cardiac surgery on CPB.

Exclusion criteria

- Age <18 years;

- Incapacitated adults;

- Emergency operation;

- Patients in need of moderate of high dosages of intravenous inotropic support (>4 gamma dobutamine or dopamine), vasopression and/or mechanical support;

- Patients with aortic have insufficiency > grade 1;
- Patients using a daily dosage of nitroglycerine or isosorbide denigrate;
- Patients using alpha blockers.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2016
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	26-01-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55621
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5520
NTR-old	NTR5647
CCMO	NL51125.058.14
OMON	NL-OMON55621

Study results