Vascular reactivity in patients with heart failure

Gepubliceerd: 26-01-2016 Laatst bijgewerkt: 15-05-2024

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-...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22119

Bron
NTR

Verkorte titel
VASOR

Aandoening

Heart failure

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: Leiden University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Change in SVR after phenylephrine administration

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

- Phenylephrine challenge

- Vasodilation test;
- Pericardial fat biopsy.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2016
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	26-01-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55621
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten